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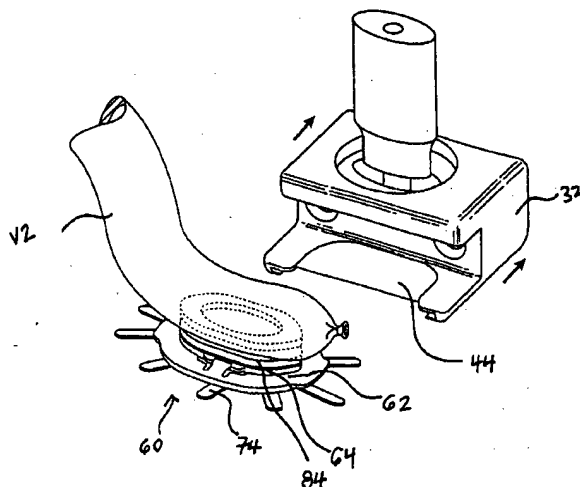
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[Continued on next page]

(54) Title: METHODS, DEVICES AND SYSTEMS FOR FORMING MAGNETIC ANASTOMOSES



(57) Abstract: Methods, devices and systems for forming magnetic anastomoses between two blood vessels. A first anastomotic component is removably supported by the distal end of a delivery device for attachment to a first vessel. The delivery device also supports a second anastomotic component that has been secured to a second blood vessel. The device is operated to secure the first component to the first vessel, couple the second component to the first component, and then release the components to complete the anastomosis. A robotic anastomosis system includes several robotic instruments that may be positioned through ports in a patient, used to secure an anastomotic component to a vessel, and then used to magnetically couple the components. Delivery devices for deploying magnetic anastomotic components include an actuator that uses magnetic repulsion to move the components into engagement with the inner and outer surfaces of the vessel wall. The anastomotic components are secured to the vessel wall by magnetic force and in addition may be secured by mechanical attachment.

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CROSS-REFERENCE TO RELATED APPLICATIONS

15 BACKGROUND OF THE INVENTION

The invention relates to forming an anastomoses between hollow anatomical structures or bodies, such as blood vessels, and more particularly, to using magnetism to form such anastomoses.

Many anastomotic couplings have been proposed as substitutes for a conventional, handsewn sutured anastomosis; they have had limited success. Such couplings are used to attach various hollow structures in the body, including blood vessels. In the vascular field, most of the proposed couplers or connectors have failed to duplicate the success of sutured anastomoses and, as such, have not been widely used or accepted.

Among the drawbacks associated with proposed anastomotic couplers are failure to achieve an acceptable patency rate, insecure or inadequate attachment of the coupler to the vessels, and the inability to produce a good anastomosis on a repeated basis.

Accordingly, there is a need in the art for methods and devices for forming a
30 non-sutured anastomosis between hollow bodies in a quick, easy and repeatable manner.

SUMMARY OF THE INVENTION

According to one embodiment, the invention provides a method for forming an anastomosis between first and second hollow bodies using magnetic force. The method includes steps of providing first and second anastomotic components that are magnetically attracted to each other and are configured to be secured to first and second hollow bodies. The first component is mounted on a delivery device while the second anastomotic component is secured to the second hollow body and then mounted on the delivery device. The first anastomotic component is secured to the first hollow body, and magnetism is used to couple the first and second anastomotic components and form an anastomosis between the first and second hollow bodies.

Another embodiment provides a method for coupling first and second magnetically attracted anastomotic components mounted on a delivery device and includes steps of providing a delivery device configured to support the anastomotic components, mounting the first component on the delivery device, and mounting the second component on the delivery device in a first position. The second component is moved to a second position and magnetism is used to couple the components.

Another embodiment provides a method for bypassing a portion of a blood vessel using magnetism. The method has steps of providing first and second anastomotic components that are magnetically attracted, respectively, to third and fourth anastomotic components, providing a graft vessel having a proximal portion adapted to be secured to a source of blood and a distal portion adapted to be secured to a target vessel so as to bypass a portion of the target vessel. Additional steps include securing the first anastomotic component to the proximal portion of the graft vessel, securing the second anastomotic component to the distal portion of the graft vessel, securing the third anastomotic component to a source of blood and securing the fourth anastomotic component to the target vessel at a location distal to the portion to be bypassed. Further steps include using magnetism to couple the first and third anastomotic components together and form a proximal anastomosis, after using magnetism to couple the second and fourth anastomotic components together to form a distal anastomosis.

Another embodiment provides a method for forming an anastomosis between first and second hollow bodies using magnetic force and includes steps of positioning a first anastomotic component on a delivery device, the first anastomotic component adapted to be secured to a first hollow body, positioning a second anastomotic component on the delivery

device, the second anastomotic component adapted to be secured to a second hollow body, wherein the first and second anastomotic components are magnetically attracted to each other and are positioned on the delivery device in an offset configuration with respect to one another. Additional steps include securing the second anastomotic component to a second
5 hollow body so as to place the opening of the second component in communication with the second hollow body, moving the first and second anastomotic components from the offset configuration into substantial alignment with each other, and using magnetism to couple the first and second anastomotic components and form an anastomosis between the first and second hollow bodies.

10 Another embodiment of the invention provides a system for forming a magnetic anastomosis between first and second hollow bodies. The system includes a delivery device and first and second anastomotic components that are magnetically attracted to one another, the components being mounted on the delivery device in a first orientation, preferably in alignment with each other. A transfer member moves at least one of the first
15 and second anastomotic components to place the components in a second relative orientation in which they are aligned.

Still another embodiment of the invention provides a system for forming a magnetic anastomosis between first and second hollow bodies. The system includes a delivery device and first and second anastomotic components that are magnetically attracted
20 to one another. The first and second anastomotic components are supported by the delivery device so as to be physically unconnected, and an actuator is used to deliver the first and second components and create a magnetic anastomosis between the two hollow bodies.

Another embodiment of the invention provides a method using robotics to form a magnetic anastomosis between first and second hollow bodies. The method includes
25 steps of providing first and second anastomotic components respectively configured to be secured to first and second hollow bodies, the first and second components being magnetically attracted to one another, using a robotic element to secure the first anastomotic component to the first hollow body, using a robotic element to secure the second anastomotic component to the second hollow body, and coupling the first and second anastomotic
30 components via magnetic force to form an anastomosis between the first and second hollow bodies.

Still another embodiment of the invention provides a robotic system for forming an anastomosis between first and second hollow bodies using magnetic force. The

system includes multiple robotic elements configured to removably support first and second anastomotic components respectively configured to be secured to first and second hollow bodies, the first and second components being magnetically attracted to one another. The first and second anastomotic components are supported by the robotic elements and a user may
5 operate the robotic system to manipulate the robotic elements to secure the first and second anastomotic components to the first and second hollow bodies, respectively, and magnetically couple the first and second anastomotic components and form an anastomosis.

Yet another embodiment of the invention provides a method for coupling first and second magnetically attracted anastomotic components that are mounted on a delivery
10 device and includes steps of providing at least first and second anastomotic components configured to be secured to a first hollow body, the first and second components being magnetically attracted to one another, providing a delivery device configured to support at least two anastomotic components, mounting the first anastomotic component on the delivery device, mounting the second anastomotic component on the delivery device, and using
15 magnetic repulsion between a portion of the delivery device and the first anastomotic component to move it toward the second anastomotic component.

Another embodiment of the invention provides a delivery device for delivering at least one magnetic anastomotic component to form an anastomosis between first and second hollow bodies. The delivery device is configured to support an anastomotic
20 component, and the anastomotic component includes at least two members magnetically attracted to one another. The two members of the anastomotic component are supported by the delivery device, and the delivery device includes an actuator that uses magnetic repulsion to move one of the members toward the other member.

25 BRIEF DESCRIPTION OF THE DRAWING FIGURES

Fig. 1A is a side elevation view of a delivery device constructed according to one embodiment of the invention;

Fig. 1B is an upper plan view of the delivery device shown in Fig. 1A;

Fig. 2A is a side elevation view of the delivery device shown in Fig. 1A with
30 the nose cone of the device in an extended position;

Fig. 2B is an upper plan view of the delivery device shown in Fig. 2A;

Fig. 2C is an upper plan view of the delivery device shown in Figs. 2A and 2B

with a cutting tip extending from the nose cone;

Fig. 3 is a perspective exploded view of a cradle disposed at the distal end of the delivery device;

5 Figs. 4A, 4B and 4C are, respectively, upper plan, side elevation, and end elevation assembly views of the cradle shown in Fig. 3;

Fig. 5 is an upper plan view of a magnetic anastomotic component constructed according to one embodiment of the invention;

10 Figs. 6A through 6G are sequential perspective views of the distal end of the delivery device being used to couple first and second anastomotic components to form an anastomosis between first and second vessels;

Figs. 7A through 7D are bottom plan views sequentially showing the delivery device being used to secure a first anastomotic component to a first vessel and then couple the first component to a second anastomotic component which is secured to a second vessel;

15 Figs. 8A through 8D are side elevation views corresponding to Figs. 7A-7D but showing a first vessel to which the first anastomotic component is being secured;

Figs. 9A through 9F are perspective views sequentially showing the use of a robotic system to form a magnetic anastomosis according to another embodiment of the invention;

20 Figs. 10A and 10B are perspective views of a delivery device constructed according to an alternative embodiment of the invention, wherein an anastomotic component is shown mounted on the delivery device prior to actuation of the device;

Figs. 11A and 11B are, respectively, fragmentary side and end elevation views of the device and anastomotic component illustrated in Figs. 10A and 10B;

25 Figs. 12A and 12B are, respectively, fragmentary side and end elevation views of the device and anastomotic component illustrated in Figs. 11A and 11B after partial actuation of the device;

Figs. 13A and 13B are, respectively, fragmentary side and end elevation views of the device and anastomotic component illustrated in Figs. 12A and 12B after further actuation of the device; and

30 Figs. 14A and 14B are side elevation views in section showing an exemplary actuator for the delivery device shown in Fig. 10A through Fig. 13B.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 shows an anastomotic delivery device 10 having a handle 12, first and second actuators 14, 16, and a shaft 18. The distal end of the delivery device 10 is indicated by the reference numeral 20 and is constructed to deploy a first anastomotic component that is configured to be coupled to a second anastomotic component, thereby forming a magnetic anastomosis. As used herein, the term anastomosis encompasses the connection of any two (or more) hollow anatomical structures, bodies, vessels, etc.

The distal end 20 of delivery device 10 is used to secure a first anastomotic component to a first vessel while supporting a second anastomotic component secured to a second vessel (the components and vessels not being shown in Figs. 1A and 1B and 2A-2C). In the illustrated embodiment the distal end 20 includes a cradle 22, which is described in detail below with reference to Figs. 3 and 4A-4C. The cradle 22 receives the second anastomotic component and a portion of the vessel to which it is attached. The delivery device 10 is used to secure the first anastomotic component to its vessel as well as magnetically couple the first and second anastomotic components to form the anastomosis.

The delivery device 10 preferably is pistol-shaped as shown, but could take alternative configurations. The first actuator 14 preferably has a safety 24 and is operably coupled to the shaft to effect distal and proximal motion of the shaft (i.e., to the left and right in Fig. 1A, respectively). The second actuator 16 is used to operate a tissue penetrating mechanism which, in the illustrated embodiment, comprises a shaft 26 with a cutting tip 28 at its distal end. The shaft 26 is spring loaded so that pressing the second actuator 16 exposes the cutting tip 28 by moving it beyond a nose cone 30. Figs. 2B and 2C show, respectively, the cutting tip 28 in a retracted position and an extended, tissue cutting position.

Fig. 3 is an exploded view of the cradle 22 of the delivery device 10. The cradle 22 includes a base 32, which may be somewhat U-shaped so as to define a space 34 along its one side. The base 32 has a bore 36 to which shaft 18 is secured, as well as a bore 38 through which an inner shaft (not shown) extends. The inner shaft (Fig. 6A) is preferably provided with an exterior configured to be complimentary to an anastomotic component (not shown) mounted thereon. The base 32 includes two ledges 40 that, along with a wall 42, partially define the space 34. The ledges 40 support a transfer member 44 that is used to align and, according to the preferred embodiment, couple magnetic anastomotic components.

The transfer member 44 is preferably a thin sheet sized to rest on the ledges 40 of the base 32. When positioned on the base 32 the transfer member 44 overlies a gap 46

located between the ledges 40. While the transfer member 44 could be formed as part of the base, in the illustrated embodiment it is a separate element that is held in position by a clamp 48. The clamp 48 is generally L-shaped with a pair of horizontal legs 50 adapted to overlie the ledges 40 of the base 32. As shown, the legs 50 define a gap that overlies the gap 46 of the base 32 when the clamp 48 is attached thereto, which leaves the transfer member 44 uncovered in that area. The clamp 48 also has a vertical leg 52 adapted to be secured to the wall 42 of the base 32 by any suitable means, for example, mating apertures 54, 56 and fasteners (not shown).

Figs. 4A, 4B and 4C show the cradle 22 with the transfer member 44 and clamp 48 attached thereto. The base 32 is configured to support an anastomotic component (not shown in Figs. 4A-4C) while it is being secured to a target vessel. The base 32 has slots 58 (Figs. 3 and 4A) which receive an anastomotic component in removable fashion.

Fig. 5 shows one preferred anastomotic component constructed according to the invention and suitable for use in forming a magnetic anastomosis. The anastomotic component 60 includes an annular base 62, a magnet 64 with an opening 66 mounted on the base, and a vessel attaching mechanism 68. The base 62 also has tabs 70 sized to be slidably received in the slots 58 of the cradle 22. The tabs 70 are slid into the slots 58 until the opening 66 of the component 60 is aligned with the bores 36, 38 of the delivery device 10.

The magnet 64 may be attached to the base 62 of the anastomotic component 60 in any suitable manner, for example, adhesively, mechanical locking, etc. In the illustrated embodiment, the base 62 has locking tabs 72 for engaging and locking the magnet 64. It will be appreciated that the specific construction of the anastomotic component may be varied from that illustrated. It will also be recognized that the anastomotic component could be removably mounted on the delivery device in manners other than described herein.

An important feature of the illustrated anastomotic component 60 facilitates improved attachment to vessels. In particular, it is desirable in some cases to use a component with an elliptical profile. The anastomotic component 60 achieves equal spacing at the tips 76 of the members 74, which requires unequal spacing of the opposite ends of the members, as shown in Fig. 5. The equally spaced tips provide increased holding force and improved sealing, as compared to a plurality of arms that are unequally spaced at their tips. This is particularly true for attachment members or arms that rely on their distal tips, as opposed to their entire length, to engage tissue.

An exemplary application for the invention will be described with reference to

Figs. 6A through 6G, wherein the delivery device 10 is used to deploy a first anastomotic component and then magnetically couple it to a second anastomotic component thereto. Fig. 6A shows the above-described distal end 20 of delivery device 10 positioned alongside the above-described magnetic anastomotic component 60 (Fig. 5). The tabs 70 of the component 60 are positioned adjacent the slots 58 in the base 32 of cradle 22.

The vessel attaching mechanism 68 of the anastomotic component 60 is shown in Fig. 6A in a collapsed orientation for loading onto the delivery device 10. The illustrated mechanism 68 includes a plurality of tissue engaging members 74 which are designed to move to an expanded orientation in order secure the anastomotic component 60 to a target vessel (omitted for clarity).

Fig. 6B shows anastomotic component 60 after the tabs 70 thereof have been fully inserted into slots 58, which aligns the opening 66 of magnet 64 with the shaft 18. The shaft 18 is moved distally until the nose cone 30 has cleared the tips 76 of the tissue engaging members 74, and then it is retracted to capture the tips 76 within a recess 78 formed in the nose cone 30. This holds the tissue engaging mechanism 68 in its collapsed orientation with the members 74 radially retracted. The actuator 14 is preferably constructed so that a single motion causes the nose cone 30 to move distally and then proximally through the component.

Fig. 6C shows a vessel V2 positioned adjacent the cradle 22 and the first anastomotic component 60 (which is in the same position illustrated in Fig. 6B). The vessel V2 has secured thereto a second anastomotic component 80 comprising magnetically attracted rings 82, 84. The rings 82, 84 are respectively positioned on the inner and outer surfaces of the vessel V2 so as to sandwich the vessel wall 86 therebetween. It should be noted that while the second anastomotic component 80 is shown secured to a side wall of the vessel V2, it could instead be secured to the end of the vessel V2, for example, by passing the vessel end through one ring, everting it around over that ring, and then positioning the other ring against the everted tissue, with magnetic attraction securing the rings to the vessel.

Fig. 6D shows the vessel V2 positioned in the space 34 defined by the cradle 22 with the second anastomotic component 80 located adjacent the transfer member 44. The outer ring 84 of component 80 is disposed on the transfer member 44 and sits between the ledges 40 of the base 32 (which define an elliptical area to receive the elliptical magnet ring). The transfer member 44 may be formed of various materials, but preferably is magnetic or ferromagnetic so that it is attracted to the magnetic anastomotic component. This magnetic attraction is used to properly orient the second anastomotic component 80 on the delivery

device 10 and, according to another aspect of the invention, to move the component 80 into alignment with the first anastomotic component.

Fig. 6E shows the device 10 after the nose cone 30 has been moved distally to release the tissue engaging members 74 of mechanism 68, as indicated by the arrows. The nose cone 30 is then moved proximally through the opening 66 of the magnet 64, as shown in Fig. 6F. Next, the cradle 22 is moved in the direction of the arrows, which moves the transfer member 44 (and the second anastomotic component 80 held thereby) toward the first anastomotic component 60. It should be noted that the cradle, rather than being square or rectangular, could be round so as to allow movement in multiple directions with respect to the anastomotic components.

Once the second anastomotic component 80 has been moved by the transfer member and is aligned with the first anastomotic component 60, the transfer member 44 is moved further in the direction of the arrows. This motion slides the transfer member 44 from in between the two components, which allows the components to become magnetically coupled. More specifically, although the second anastomotic component 80 is magnetically held against the transfer member 44, its attraction to the first component 60 is much stronger. As a result, the transfer member 44 releases the second anastomotic component 80, which leaves the components 60, 80 in face-to-face contact, as shown in Fig. 6G. Fig. 6G shows the tissue engaging members 74 in their expanded position, in which they cooperate with the component base 62 to compress the target vessel tissue (omitted for clarity) and secure the first anastomotic component 60 thereto.

Figs. 7A-7D are bottom plan views sequentially illustrating the members 74 of the first anastomotic component 60 being expanded, the transfer member 44 being used to move the outer ring 84 of the second anastomotic component 80 into alignment with the magnet 64 of the component 60, and the transfer member 44 being slid from between the two anastomotic components. When the tabs 70 clear the slots 58 the transfer member 44 should be moved from beneath the component 80, which ensures that the delivery device 10 will not be pulled away and lift the component 80 from the component 60.

Figs. 8A-8D are sectional views corresponding to Figs. 7A-7D, but showing a first vessel V1 to which the first anastomotic component 60 is being secured. (The second vessel V2 is omitted from these views for clarity.) Figs. 8C and 8D illustrate another aspect of the invention wherein the opening extending into the vessel V defined by the anastomotic component 60 is sealed during alignment of the components.

Fig. 8C shows the transfer member 44 partially over the opening 66 of component 60 (with the shaft and nose cone over the rest of the opening). In this position, blood is blocked by the transfer member 44, although some blood may enter the bore that receives shaft 18. The blood could be blocked instead, or a flashback lumen could be provided if desired. Fig. 8D shows the transfer member 44 after it has been further moved to align the first and second anastomotic components 60, 80. In this position, the transfer member 44 is disposed between the components 60, 80 and blocks blood flow out of the vessel V2. From the position of Fig. 8D the transfer member 44 is slid out to couple the components 60, 80.

According to another embodiment of the invention, a robotic system is used to form a magnetic anastomosis. Referring to Figs. 9A-9F, a delivery device 90 is schematically shown and has mounted thereon an anastomotic component 92. A pair of robotic elements 94, 96 is provided with one or more jaw or pincer mechanisms. Fig. 9A shows robotic element 94 stabilizing a target vessel V1 (for example, a coronary artery) while the element 96 holds the delivery device 90.

As shown, an incision or other opening has been formed in the vessel wall, either by robotics or manually. The opening is sized to receive the distal end of the delivery device 90 and the anastomotic component 92, as shown in Fig. 9B. (The robotic element holding the delivery device is omitted from Figs. 9C and 9D for clarity.) Fig. 9C shows the anastomotic component 92 located in the lumen of the vessel V1 while another anastomotic component 98 is moved toward the vessel wall. An actuator 100 moves the anastomotic component 98 toward the component 92 until magnetic attraction causes the two components to sandwich the wall of vessel V1. The actuator 100 may be moved manually or by one of the robotic elements.

Fig. 9D shows the delivery device 90 being subsequently removed and the resulting port that is formed in the vessel V1. The delivery device 90 is provided with a mechanism (not shown) that it actuated to release the anastomotic components once they have been secured to the vessel and coupled to place the vessels in fluid communication. The delivery device 90 may have a component release mechanism constructed according to the teachings of abovementioned application serial no. 09/638,805, the subject matter of which has been incorporated by reference herein.

Fig. 9E shows another pair of robotic elements 102, 104 being used to approximate a second vessel V2 with the first vessel V1, the latter having a magnetic port

formed by an anastomotic component 106. Approximating the vessels V1, V2 brings the anastomotic components 98, 106 toward each other until they are coupled by magnetic attraction to form the anastomosis, as shown in Fig. 9F.

It should be recognized that practicing this embodiment of the invention does not require the use of a specialized robotic system. To the contrary, any suitable robotic system may be used, for example, one of the known computerized surgical systems for performing various medical procedures. Those skilled in the art will nonetheless appreciate that in some applications it may be desirable or necessary to adapt an available robotic system for use with the delivery devices and anastomotic components of the present invention.

For example, in the embodiment of Figs. 9A through 9F, the delivery device 90 is held by the end effector (pincer jaws) of the robotic element 96. Alternatively, the delivery device of the invention may be formed as an integral part of the robotic element, for example, the end effector of the robotic element may be in the form of an anastomotic delivery device. The robotic elements may include, in addition to a delivery device, pincer jaws, graspers or other known structure for holding, manipulating and actuating the delivery device. Finally, rather than forming a portion of the robotic element as the delivery device, one or more selected features of an inventive delivery device could be included in an otherwise conventional robotic element.

It should also be recognized that the number and type of functions performed by the robotic elements may vary from procedure to procedure. In the embodiment of Figs. 9A through 9F, the robotic elements are first used to position and actuate the delivery device to secure each anastomotic component to its vessel. Next, the robotic elements are used to grasp and approximate the vessels and couple the components to complete the anastomosis.

The anastomosis could alternatively be carried out without using the robotic system to perform each step of the procedure. For example, the robotic elements may be used to hold and position, but not actuate, the delivery devices. As an example, a minimally invasive procedure may be carried out using several robotic elements inserted through small ports in the patient to hold the delivery devices in the desired position. The surgeon could then actuate a delivery device without using robotics, for instance, by passing pass the shaft of a remotely-operated instrument (such as a cable-actuated device of the type used in laparoscopic surgery) through a port to a position adjacent the delivery device. The surgeon could then operate the instrument from outside the patient's body to actuate the delivery device and deploy the anastomotic components.

As noted above, it should be appreciated that the delivery device illustrated in Figs. 9A through 9F is an exemplary embodiment and represents only one possible means for practicing the invention. Figs. 10A through 13B show a delivery device, designated by reference numeral 110, which is constructed according to another embodiment of the invention. The delivery device 110 is configured to be used in a robotic procedure and has a small profile to permit use in a minimally invasive procedure. The relatively small size of the delivery device 110 permits it to be introduced into a patient's body through a small incision or port unlike devices designed for use in more open surgical procedures. Although the delivery device 110 is constructed to be held by a robotic element such as that shown in Figs. 9A through 9F, it may also be used with a manually operated surgical instrument.

Referring to Figs. 10A and 10B, the delivery device 110 comprises a body 112 having upper and lower portions 114, 116 configured to support, respectively, first and second anastomotic components 118, 120. The delivery device 110 has an actuator 122 which deploys and then releases the components 118, 120. The upper portion 114 of the delivery device 110 is provided with a retainer 124 that holds the anastomotic component 118 until the component 120 has been properly positioned with respect to the opening in the vessel. Next, the actuator 122 is used to release the first component 118 from the retainer 124 and allow it to be coupled to the second component 120. The second component 120 is held on the delivery device 110 by a retainer 126 located on the lower portion 116 of the body 112. Further actuation of the actuator 122 releases the second component 120 (as well as the first component 118 coupled thereto) from the retainer 126 to remove the delivery device.

Figs. 10A, 10B, 11A and 11B show the delivery device 110 prior to actuation with the anastomotic components 118, 120 being held in place by the retainers 124, 126, respectively. The body 112 has a bore 128 in which a plunger 130 is slidably received, the plunger having the retainer 126 at its distal end. A spring 132 biases the plunger in a proximal direction which forces a pair of tabs 134 of retainer 124 away from the upper portion 114 of the device body 112. In this position the tabs 134 contact the lower surface of the first anastomotic component 118 and hold it away from the second component 120.

The actuator 122 is depressed to move the plunger 130 distally, which causes the tabs 134 to retract into the body 112 of the delivery device 110. As a result, the first anastomotic component 118 is no longer retained as it is in Figs. 11A and 11B, but rather is free to be moved to a coupling position. In a preferred embodiment the delivery device utilizes magnetic repulsion to couple the anastomotic components.

The illustrated delivery device 110 includes an annular magnet 135 mounted on the upper portion 114 of the device body 112 adjacent the first anastomotic component 118. The magnet 135 is preferably a permanent magnet that is oriented on the device body to have the same polarity as the adjacent anastomotic component 118. Consequently, once the
5 tabs 134 of retainer 124 are retracted into the device body 212, the first anastomotic component 118 is repelled by magnet 135 toward the outer surface of the vessel wall.

Figs. 12A and 12B show the delivery device 110 after the actuator 122 has been partially actuated to retract the tabs 134 and the anastomotic component 118 has been repelled by the magnet 135. Figs. 13A and 13B show the delivery device 110 after the
10 actuator 122 has been further actuated to release the first and second anastomotic components 118, 120 from the retainer 126 and allow the delivery device to be removed.

As shown best in Fig. 13A, the body 112 of the delivery device 110 has a sloped surface 136, while the retainer 126 has a similarly shaped surface 138. Moving the plunger 130 distally moves the retainer 126 distally from the position shown in Figs. 12A and
15 12B. This slides the ramped surface 138 of the retainer 126 along the sloped surface 136 of the device body 112, which moves the retainer 126 laterally toward the center of the device 110 (to the right in Fig. 11A) and out of engagement with the component 120 as well as the component 118.

Figs. 14A and 14B illustrate in schematic fashion the principle behind one
20 possible means for releasing the anastomotic components from the delivery device according to the invention. A delivery device 140 has a body 142 provided with a bore 144 which slidably receives a plunger or shaft 146. The distal end of the device body 142 has a ramped surface 148 configured to slide along a ramped surface 150 formed on a retainer 152 carried by the plunger 146. Fig. 14A shows a magnetic anastomotic component 154 mounted on the
25 distal end of the delivery device body 142 with the retainer 152 in its engaged position. As indicated by the arrow, the retainer 152 and the distal end of the delivery device body 142 combine to securely engage the inner diameter of the anastomotic component 154.

Actuation of the delivery device 140 moves the plunger 146 and retainer 152 distally from the position of Fig. 14A to the position of Fig. 14B. This slides the ramped
30 surface 150 on the retainer 152 along the ramped surface 148 on the body 142 of the delivery device 140. Sliding the ramped surface 150 along the surface 148 moves the retainer 152 laterally (to the right in Figs. 14A and 14B) and decreases its profile as indicated by the arrow. This disengages the retainer 152 from the inner diameter of the anastomotic component 154.

It should be appreciated that the ramped surfaces shown in the illustrated embodiment represent only one possible way to transmit motion from an actuator to the working end of the delivery device in order to form an anastomosis according to the invention

5 The magnetically attracted anastomotic components of the invention are adapted to be placed on opposite surfaces of a vessel wall and to sandwich the wall due to magnetic force. In some applications it may be desirable to provide one or more of the anastomotic components with additional or different vessel securing means; for example, the component may be attached to the vessel mechanically (e.g. by suturing) instead of or in addition to magnetically. The suture could be passed around the body of the anastomotic
10 component and through the vessel wall, or the component could be provided with one or more suture anchors, for example, at spaced locations around its perimeter. The specific number, size, and location of suture anchors on the anastomotic component may of course vary depending on the application and user preference.

Other features, aspects and advantages of the invention beyond those
15 specifically discussed will be apparent to those skilled in the art. Many modifications, alterations and variations of the illustrated embodiments may be made without departing from the scope and spirit of the invention as defined by the claims.

WHAT IS CLAIMED IS:

- 1 1. A method for forming an anastomosis between first and second hollow
2 bodies using magnetic force, the method comprising steps of:
3 providing first and second anastomotic components respectively configured to
4 be secured to first and second hollow bodies, the first and second components being
5 magnetically attracted to one another;
6 mounting the first component on a delivery device;
7 securing the second anastomotic component to the second hollow body;
8 mounting the second anastomotic component on the delivery device with the
9 second hollow body secured to the second component;
10 securing the first anastomotic component to the first hollow body; and
11 using magnetism to couple the first and second anastomotic components and
12 form an anastomosis between the first and second hollow bodies.
- 1 2. The method of claim 1, wherein the first and second hollow bodies are
2 blood vessels.
- 1 3. The method of claim 2, wherein the first component is mounted on the
2 delivery device in a collapsed configuration.
- 1 4. The method of claim 2, wherein the second anastomotic component is
2 magnetically mounted on the delivery device.
- 1 5. The method of claim 4, wherein the second anastomotic component is
2 mounted on a ferromagnetic sheet supported by the delivery device.
- 1 6. The method of claim 5, wherein the ferromagnetic sheet is manipulated
2 to move the second anastomotic component into alignment with the first anastomotic
3 component.
- 1 7. The method of claim 2, further comprising forming an opening in the
2 first blood vessel prior to securing the first anastomotic component thereto.
- 1 8. The method of claim 7, wherein the opening is formed by an incising
2 element carried by the delivery device.

1 9. The method of claim 2, wherein the delivery device has a cradle and a
2 portion of the second hollow body is received in and supported by the cradle.

1 10. The method of claim 2, wherein the first anastomotic component has
2 tabs received in slots formed in the delivery device.

1 11. The method of claim 2, wherein the first and second anastomotic
2 components are coupled to form a side-to-side anastomosis between the first and second
3 blood vessels.

1 12. A method for coupling first and second magnetically attracted
2 anastomotic components mounted on a delivery device, the method comprising steps of:
3 providing first and second anastomotic components respectively configured to
4 be secured to first and second hollow bodies, the first and second components being
5 magnetically attracted to one another;
6 providing a delivery device configured to support the first and second
7 anastomotic components;
8 mounting the first anastomotic component on the delivery device;
9 mounting the second anastomotic component on the delivery device in a first
10 position;
11 moving the second anastomotic component from the first position to a second
12 position; and
13 using magnetism to couple the first and second anastomotic components.

1 13. The method of claim 12, wherein the delivery device has a transfer
2 member holding the second anastomotic component, and the moving step is performed by
3 moving the transfer member and second anastomotic component from the first position
4 toward the first anastomotic component.

1 14. The method of claim 13, wherein the transfer member is moved until
2 the first and second anastomotic components are aligned, and then is moved further to release
3 the second anastomotic component from the delivery device.

1 15. The method of claim 14, wherein moving the transfer member further
2 also releases the first anastomotic component from the delivery device.

1 16. The method of claim 14, wherein moving the transfer member allows
2 the first and second anastomotic components to magnetically engage each other.

1 17. The method of claim 16, wherein the transfer member is moved to
2 align and release the first and second anastomotic components.

1 18. The method of claim 13, wherein the second anastomotic component is
2 magnetically attracted to the transfer member and is held in the first position by magnetic
3 force.

1 19. The method of claim 18, wherein the transfer member is a sheet having
2 ferromagnetic properties and the second anastomotic component comprises a permanent
3 magnet attracted to the sheet.

1 20. A method for bypassing a portion of a blood vessel using magnetism,
2 the method comprising steps of:

3 providing first and second anastomotic components that are magnetically
4 attracted, respectively, to third and fourth anastomotic components;

5 providing a graft vessel having a proximal portion adapted to be secured to a
6 source of blood and a distal portion adapted to be secured to a target vessel so as to bypass a
7 portion of the target vessel;

8 securing the first anastomotic component to the proximal portion of the graft
9 vessel and securing the second anastomotic component to the distal portion of the graft
10 vessel;

11 securing the third anastomotic component to a source of blood and securing
12 the fourth anastomotic component to the target vessel at a location distal to the portion to be
13 bypassed;

14 using magnetism to couple the first and third anastomotic components together
15 and form a proximal anastomosis; and

16 using magnetism to couple the second and fourth anastomotic components
17 together to form a distal anastomosis, wherein the distal anastomosis is formed before the
18 proximal anastomosis.

1 21. The method of claim 20, wherein the blood source is the aorta and the
2 target vessel is a coronary artery.

1 22. The method of claim 21, wherein the first and third anastomotic
2 components are coupled without entering the lumen of the graft vessel.

1 23. The method of claim 21, wherein the third anastomotic component is
2 secured to the aorta by a mechanical attachment.

1 24. The method of claim 21, wherein the graft vessel is an autologous
2 blood vessel.

1 25. A method for forming an anastomosis between first and second hollow
2 bodies using magnetic force, the method comprising steps of:

3 positioning a first anastomotic component on a delivery device, the first
4 anastomotic component adapted to be secured to a first hollow body;

5 positioning a second anastomotic component on the delivery device, the
6 second anastomotic component adapted to be secured to a second hollow body, wherein the
7 first and second anastomotic components are magnetically attracted to each other and are
8 positioned on the delivery device in an offset configuration with respect to one another;

9 securing the second anastomotic component to a second hollow body so as to
10 place the opening of the second component in communication with the second hollow body;

11 moving the first and second anastomotic components from the offset
12 configuration into substantial alignment with each other; and

13 using magnetism to couple the first and second anastomotic components and
14 form an anastomosis between the first and second hollow bodies.

1 26. The method of claim 25, wherein magnetic attraction between the
2 delivery device and at least one of the first and second anastomotic components is used to
3 move the components from the offset configuration.

1 27. A system for forming a magnetic anastomosis between first and second
2 hollow bodies, the system comprising:
3 a delivery device;
4 a first anastomotic component;
5 a second anastomotic component, the first and second anastomotic
6 components being magnetically attracted to one another;
7 wherein the first and second anastomotic components are mounted on the
8 delivery device in a first relative orientation; and
9 a transfer member for moving at least one of the first and second anastomotic
10 components to place the components in a second relative orientation.

1 28. The method of claim 27, wherein the transfer member comprises either
2 magnetic or ferromagnetic material.

1 29. The method of claim 28, wherein the transfer member is a thin sheet of
2 stainless steel.

1 30. The method of claim 27, wherein the first and second anastomotic
2 components are generally unaligned when in the first relative position and generally aligned
3 when in the second relative position.

1 31. A system for forming a magnetic anastomosis between first and second
2 hollow bodies, the system comprising:
3 a delivery device;
4 a first anastomotic component;
5 a second anastomotic component, the first and second anastomotic
6 components being magnetically attracted to one another;
7 wherein the first and second anastomotic components are supported by the
8 delivery device so as to be physically unconnected; and
9 an actuator for delivering the first and second anastomotic components and
10 creating a magnetic anastomosis between first and second hollow bodies

1 32. The system of claim 31, wherein the tissue penetrating element is
2 selected from the group consisting of incising, punching and coring members or mechanism.

1 33. A method for using robotics to form a magnetic anastomosis between
2 first and second hollow bodies, the method comprising steps of:
3 providing first and second anastomotic components respectively configured to
4 be secured to first and second hollow bodies, the first and second components being
5 magnetically attracted to one another;
6 using a robotic element to secure the first anastomotic component to the first
7 hollow body;
8 using a robotic element to secure the second anastomotic component to the
9 second hollow body;
10 coupling the first and second anastomotic components via magnetic force to
11 form an anastomosis between the first and second hollow bodies.

1 34. The method of claim 33, wherein the first and second hollow bodies
2 are blood vessels.

1 35. The method of claim 34, wherein at least one robotic element is used to
2 magnetically couple the first and second anastomotic components.

1 36. The method of claim 34, wherein first and second robotic elements are
2 used to secure, respectively, the first and second anastomotic components to the first and
3 second blood vessels.

1 37. The method of claim 36, wherein the first and second robotic elements
2 respectively support first and second delivery devices on which are mounted the first and
3 second anastomotic components.

1 38. The method of claim 37, wherein at least one of the first and second
2 delivery devices is separate from the robotic element and is releasably held thereby.

1 39. The method of claim 37, wherein the first anastomotic component
2 comprises at least two members magnetically attracted to each other, the two members being
3 mounted on the first delivery device.

1 40. The method of claim 39, wherein the first delivery device includes an
2 actuator for moving one of the two members toward the other of the two members.

1 41. The method of claim 40, wherein the actuator includes a magnet
2 oriented on the delivery device so as to magnetically repel the one member toward the other
3 member.

1 42. A robotic anastomosis system for forming a magnetic anastomosis
2 between first and second hollow bodies using magnetic force, the system comprising:
3 at least two robotic elements configured to support first and second
4 anastomotic components that are respectively configured to be secured to first and second
5 hollow bodies;
6 first and second anastomotic components supported by the robotic elements,
7 the first and second anastomotic components being magnetically attracted to one another; and
8 a control device operable to manipulate the robotic elements and respectively
9 secure the first and second anastomotic components to the first and second hollow bodies,
10 whereby the anastomotic components may then be coupled via magnetic attraction to form an
11 anastomosis.

1 43. The system of claim 42, wherein the control device is operable to
2 couple the first and second anastomotic components and form the anastomosis.

1 44. The system of claim 43, wherein the first and second anastomotic
2 components are mounted on first and second delivery devices, the delivery devices being
3 supported by the robotic elements.

1 45. The system of claim 44, wherein the delivery devices are separate from
2 the robotic elements so as to be releasable therefrom.

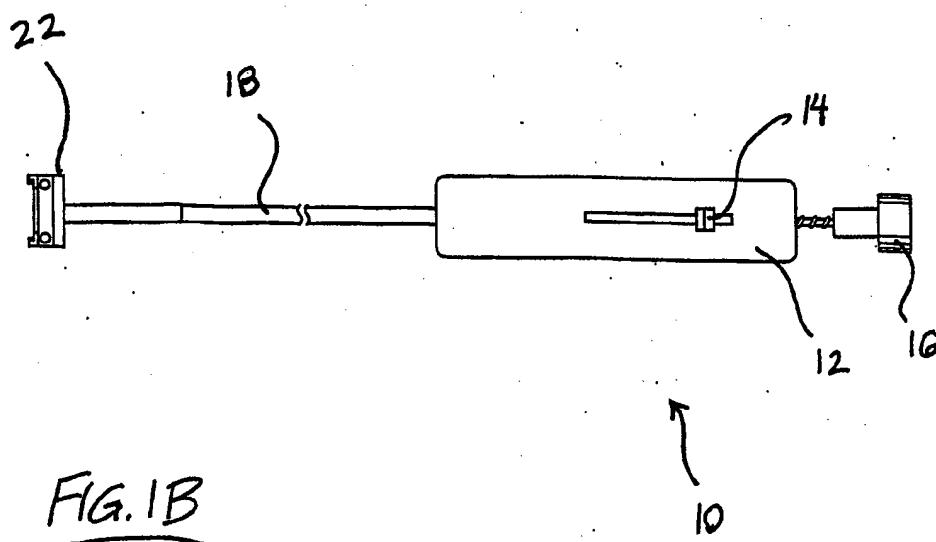
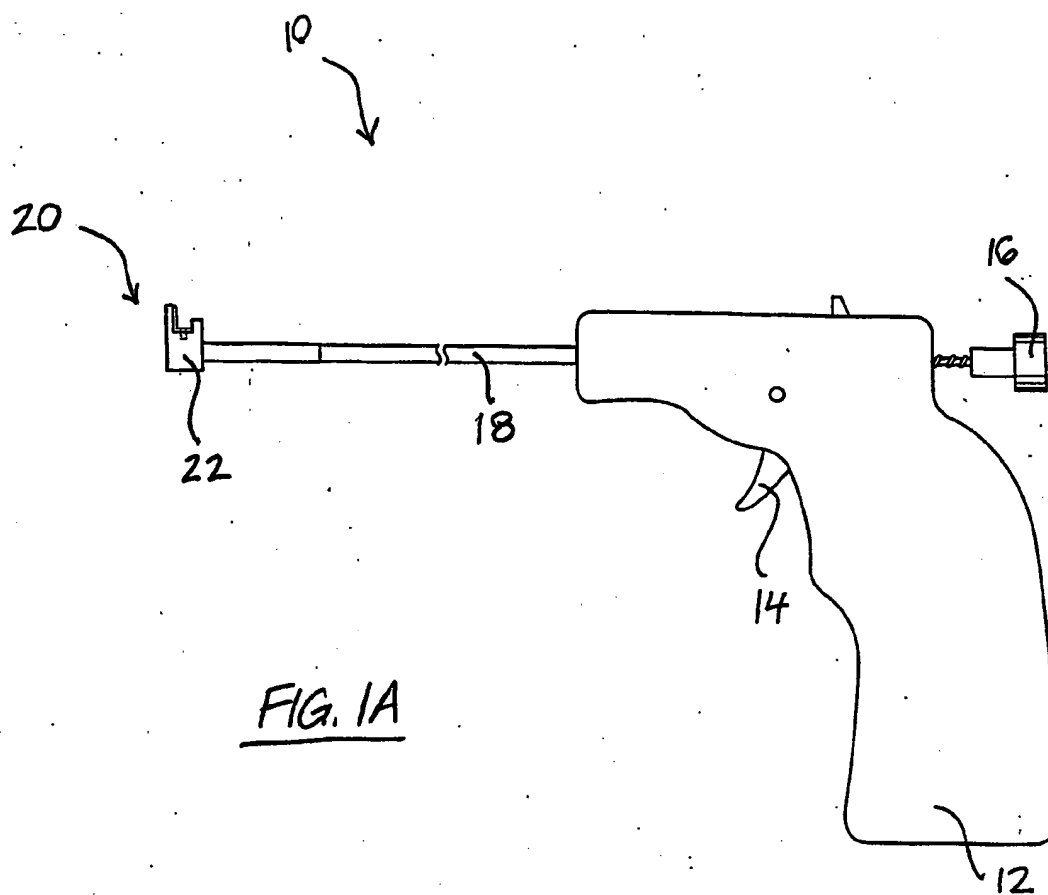
1 46. A method for coupling first and second magnetically attracted
2 anastomotic components, the method comprising steps of:
3 providing at least first and second anastomotic components configured to be
4 secured to a first hollow body, the first and second components being magnetically attracted
5 to one another;
6 providing a delivery device;
7 mounting the first anastomotic component on the delivery device;
8 mounting the second anastomotic component on the delivery device; and
9 using magnetic repulsion between a portion of the delivery device and the first
10 anastomotic component to move the first anastomotic component toward the second
11 anastomotic component.

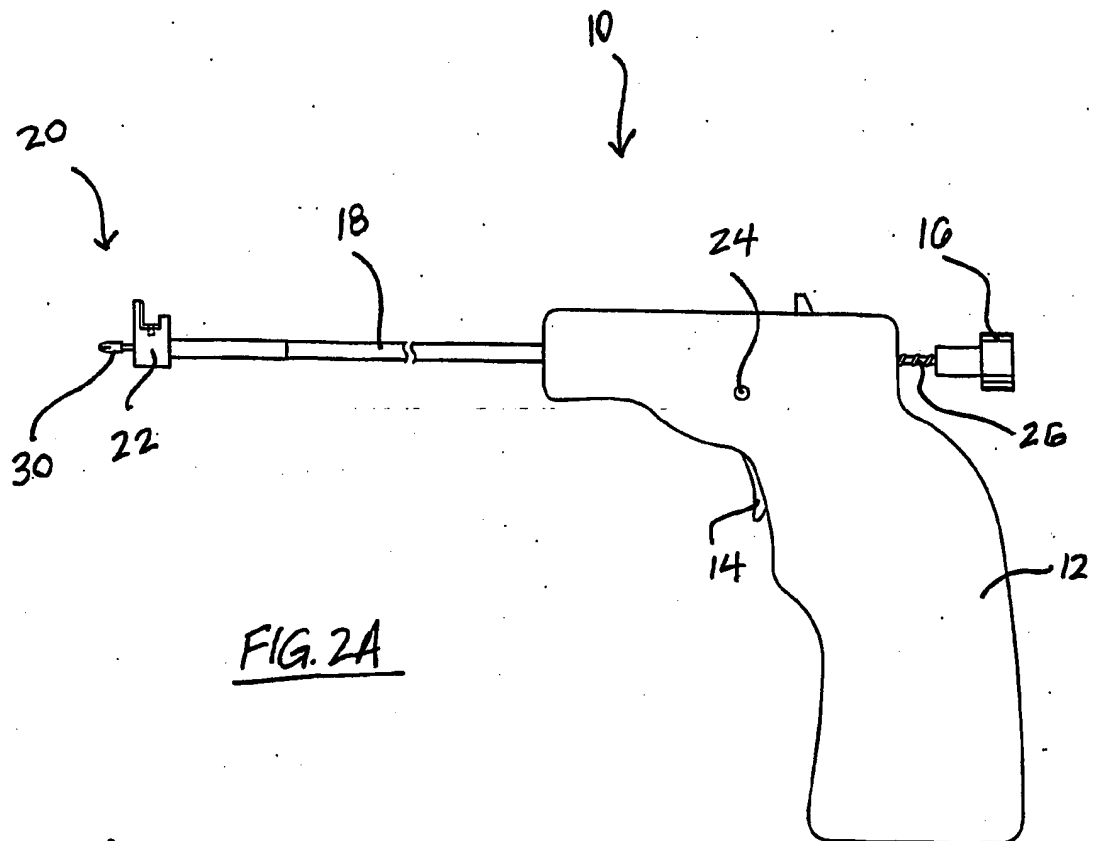
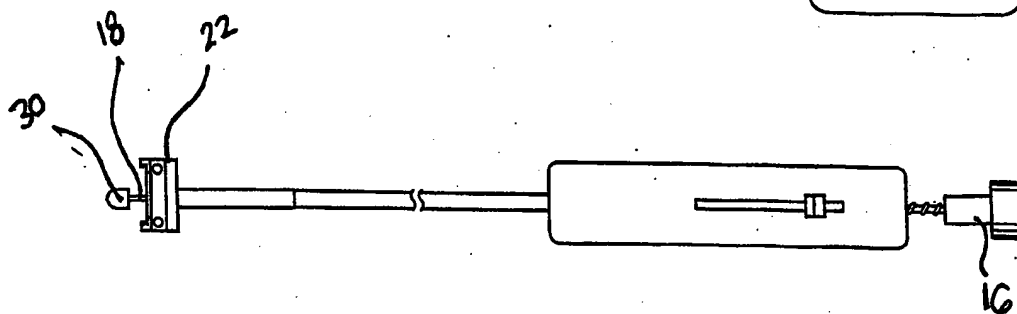
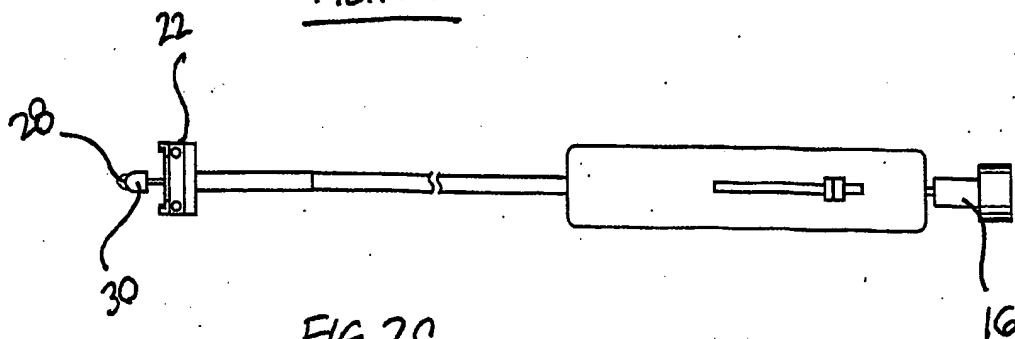
1 47. The method of claim 46, wherein the delivery device includes a
2 permanent magnet oriented to repel the first anastomotic component.

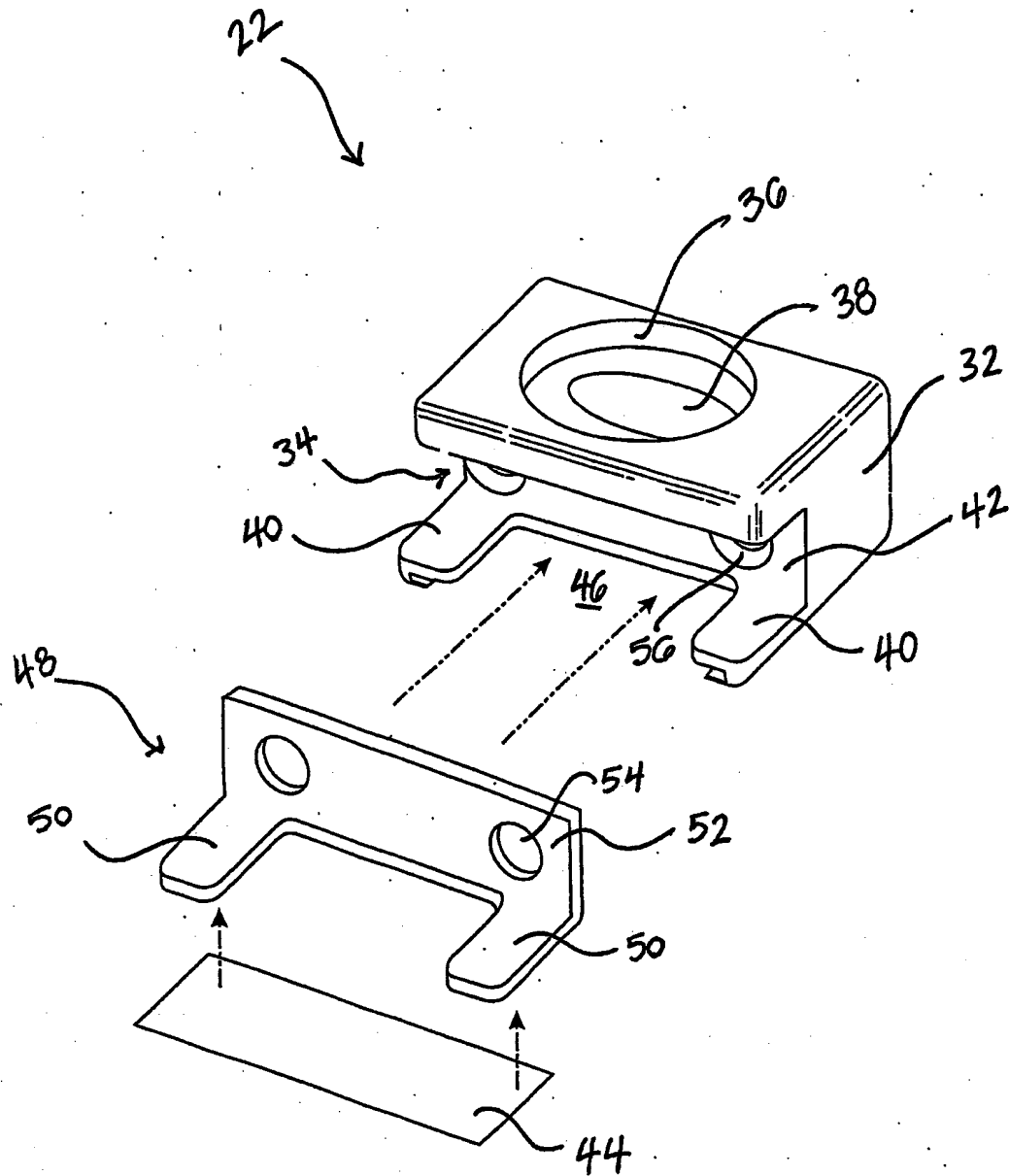
1 48. The method of claim 46, wherein only the first and second anastomotic
2 components are mounted on the delivery device.

1 49. A delivery device in combination with a magnetic anastomotic
2 component, the combination comprising:
3 an anastomotic component comprising at least two members magnetically
4 attracted to each other;
5 a delivery device supporting the two members of the anastomotic component;
6 an actuator that uses magnetic repulsion to move one of the two members
7 toward the other of the two members.

1 50. The combination of claim 49, wherein the one member has magnetic
2 properties and the actuator includes a permanent magnet, the permanent magnet being
3 oriented on the actuator so as to repel the one member toward the other member



FIG. 2AFIG. 2BFIG. 2C

FIG. 3

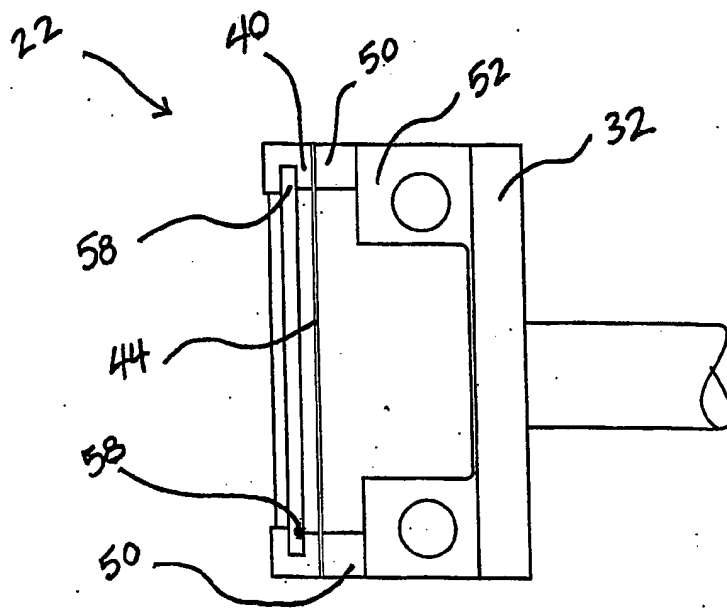


FIG. 4A

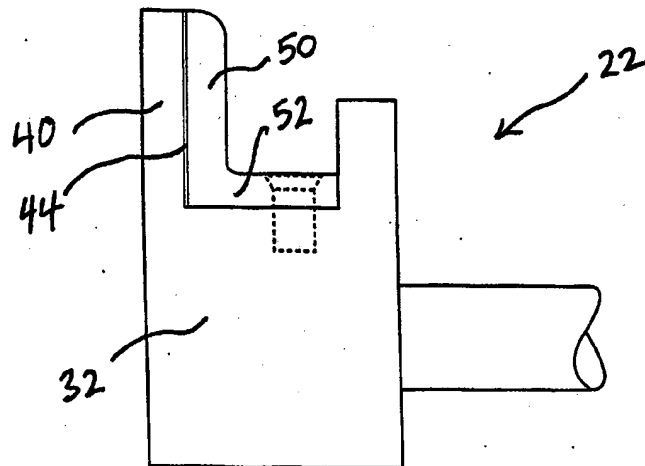


FIG. 4B

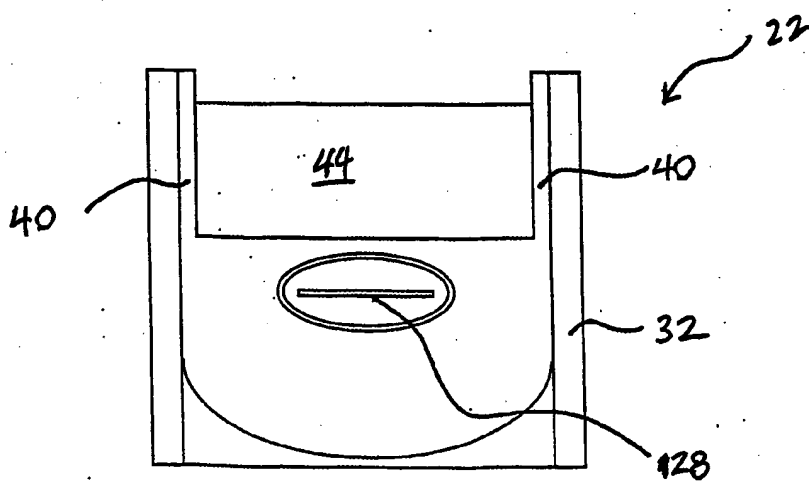
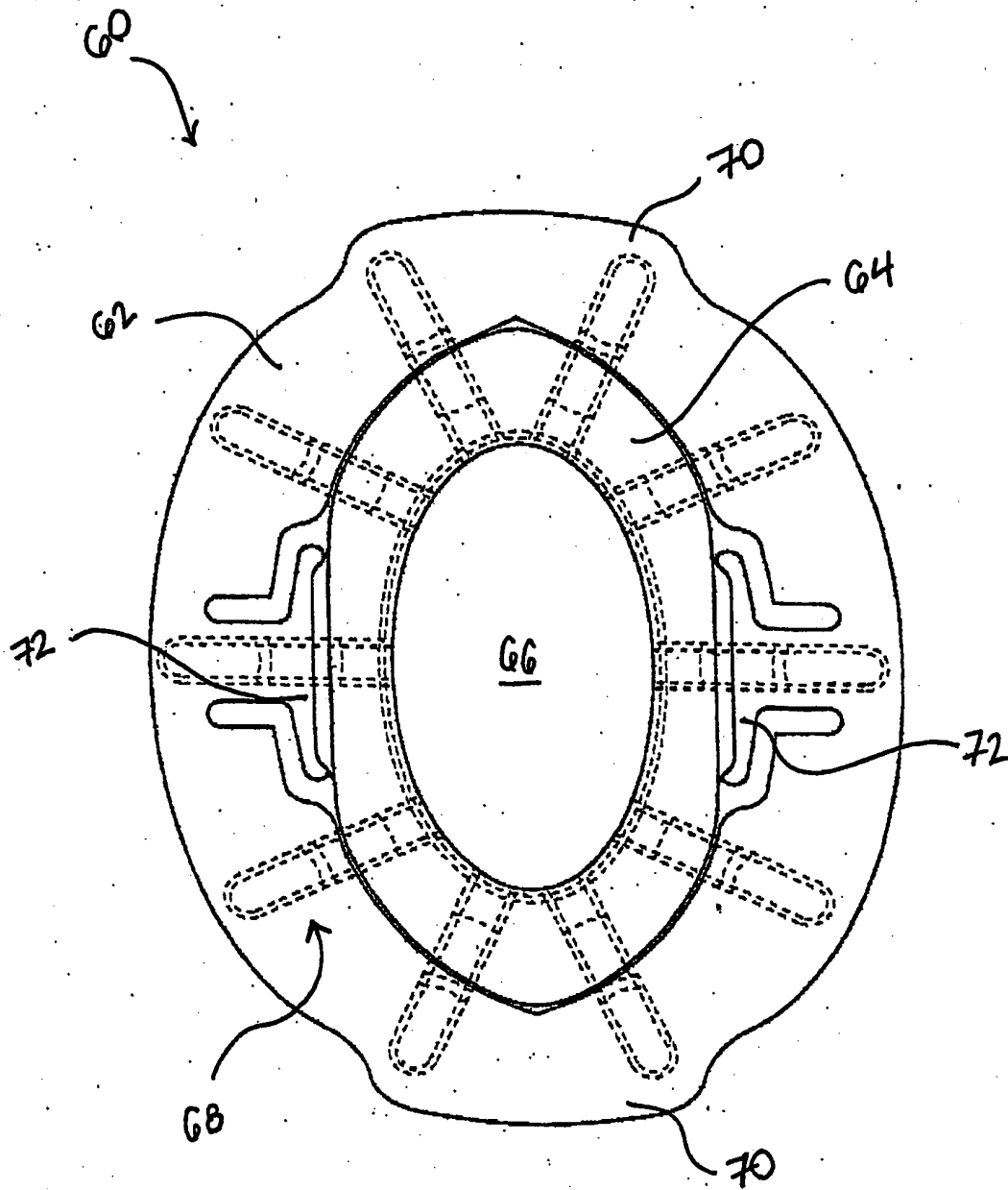
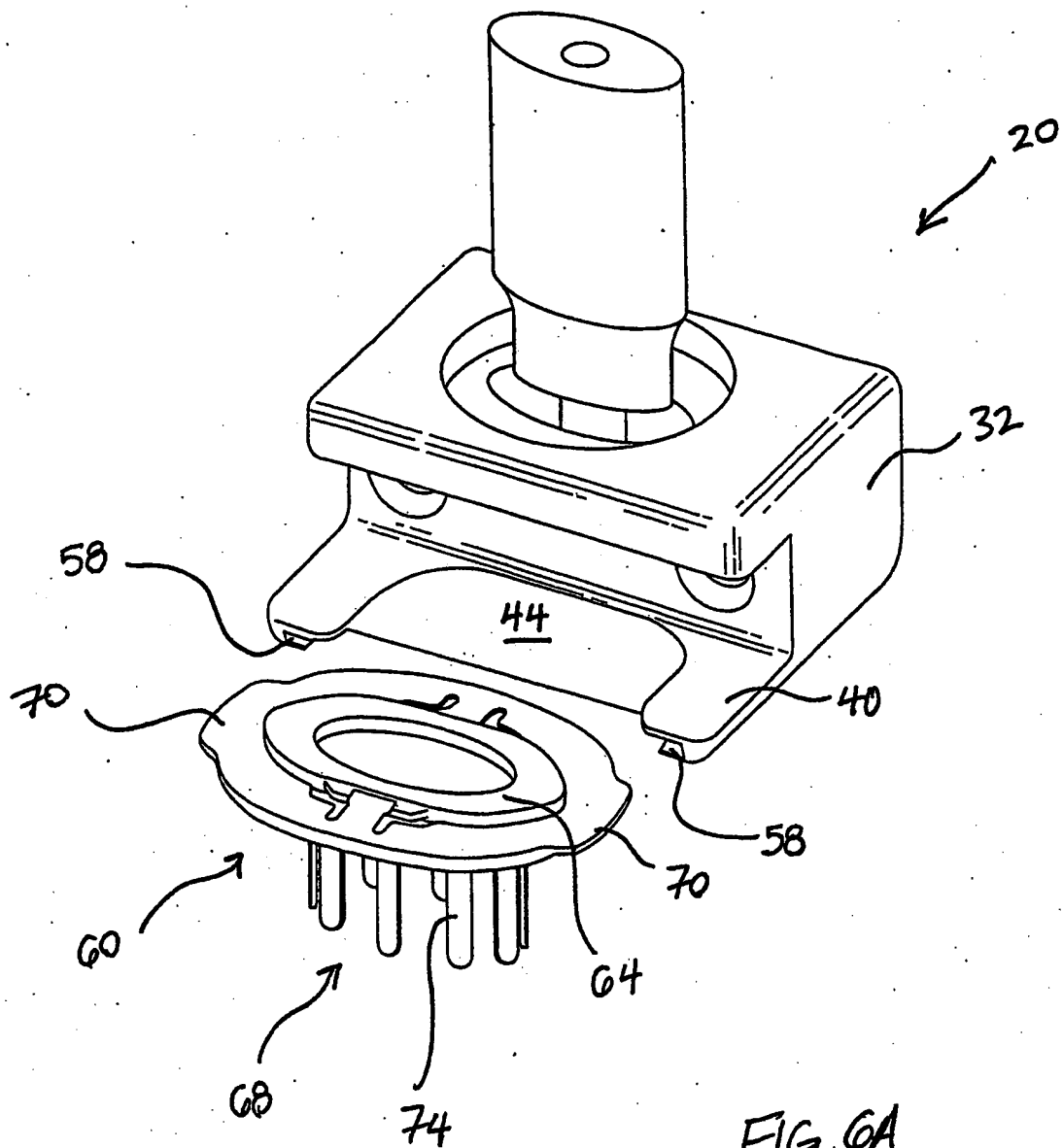


FIG. 4C

FIG. 5



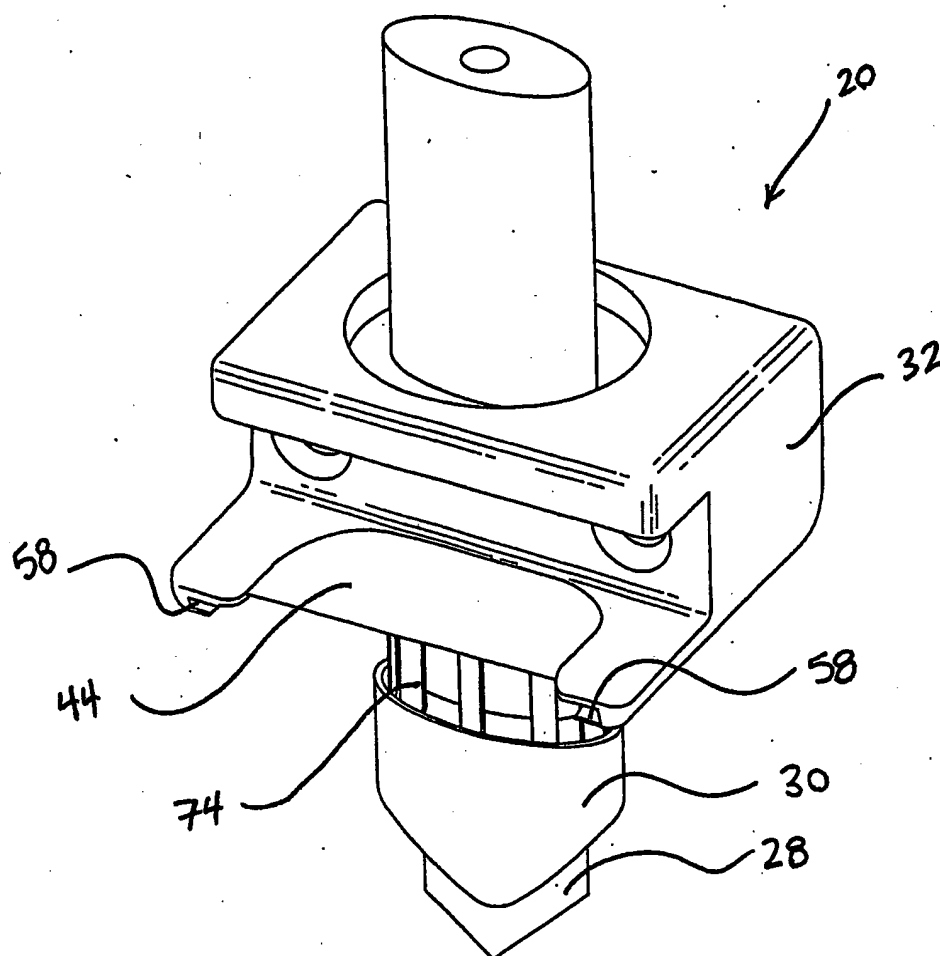


FIG. 6B

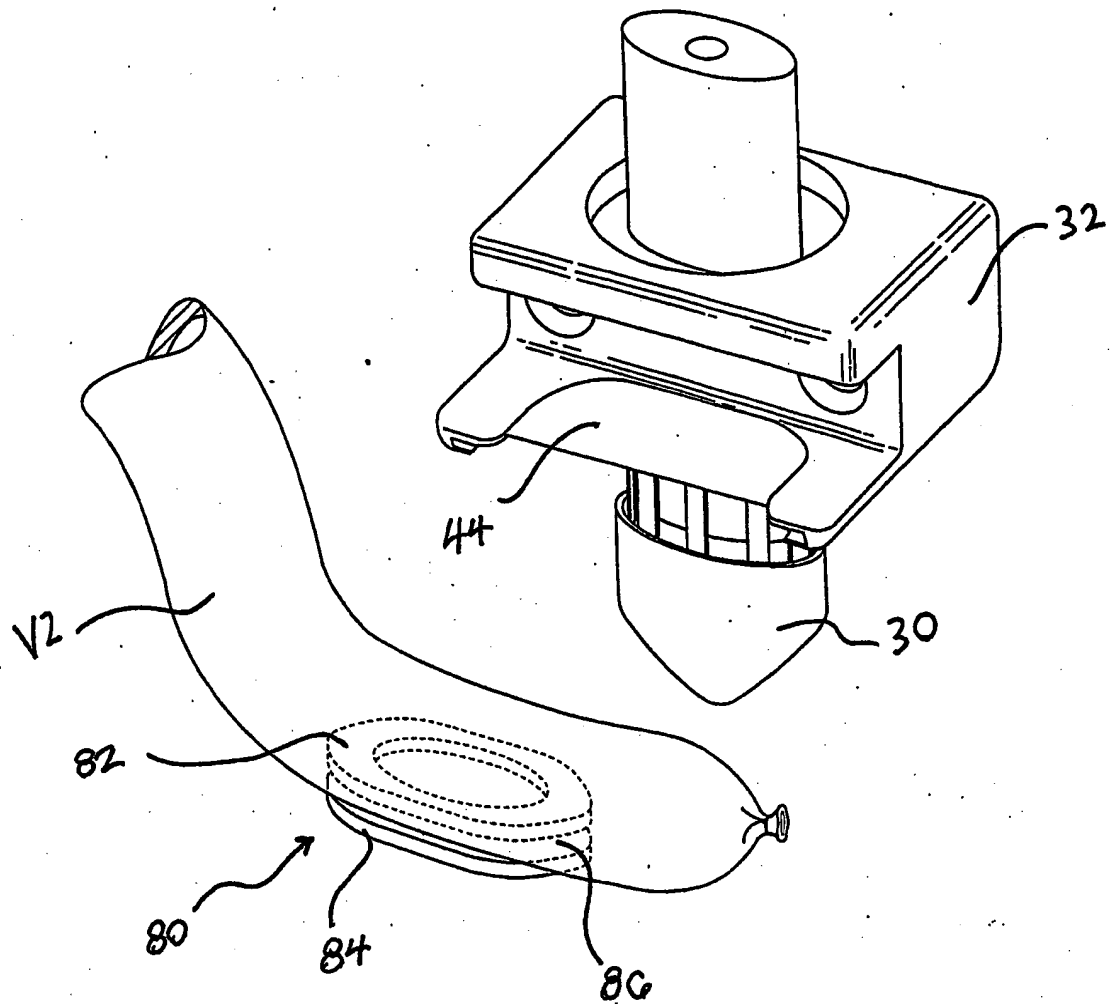
FIG. 6C

FIG. 6D

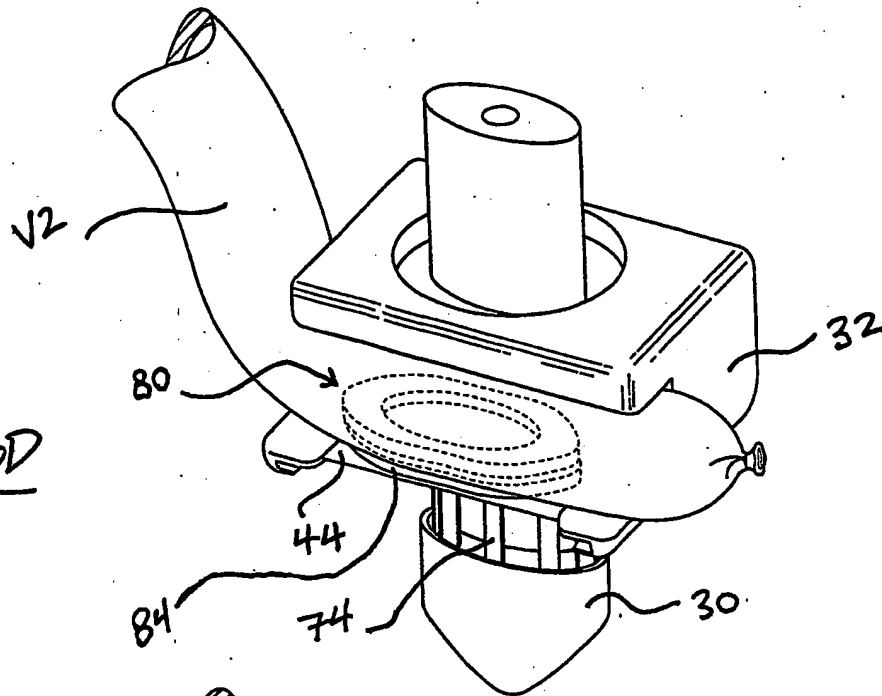


FIG. 6E

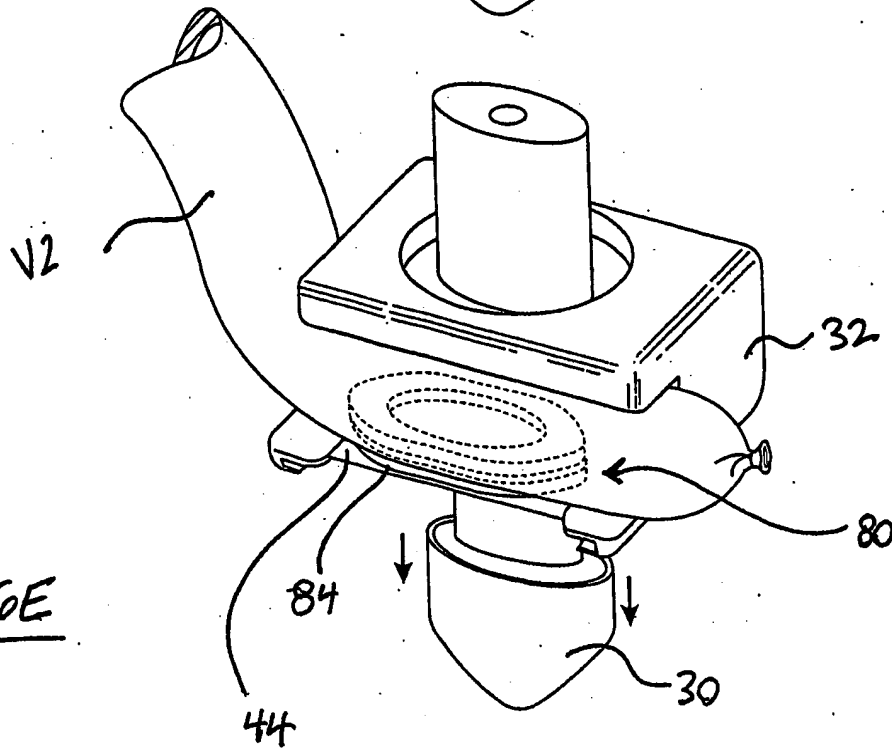


FIG. 6F

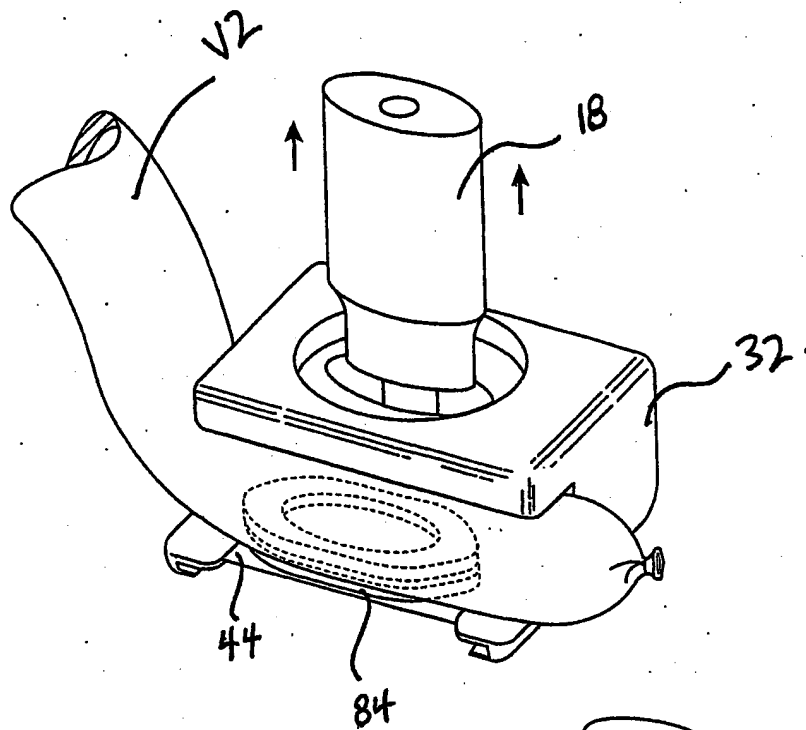


FIG. 6G

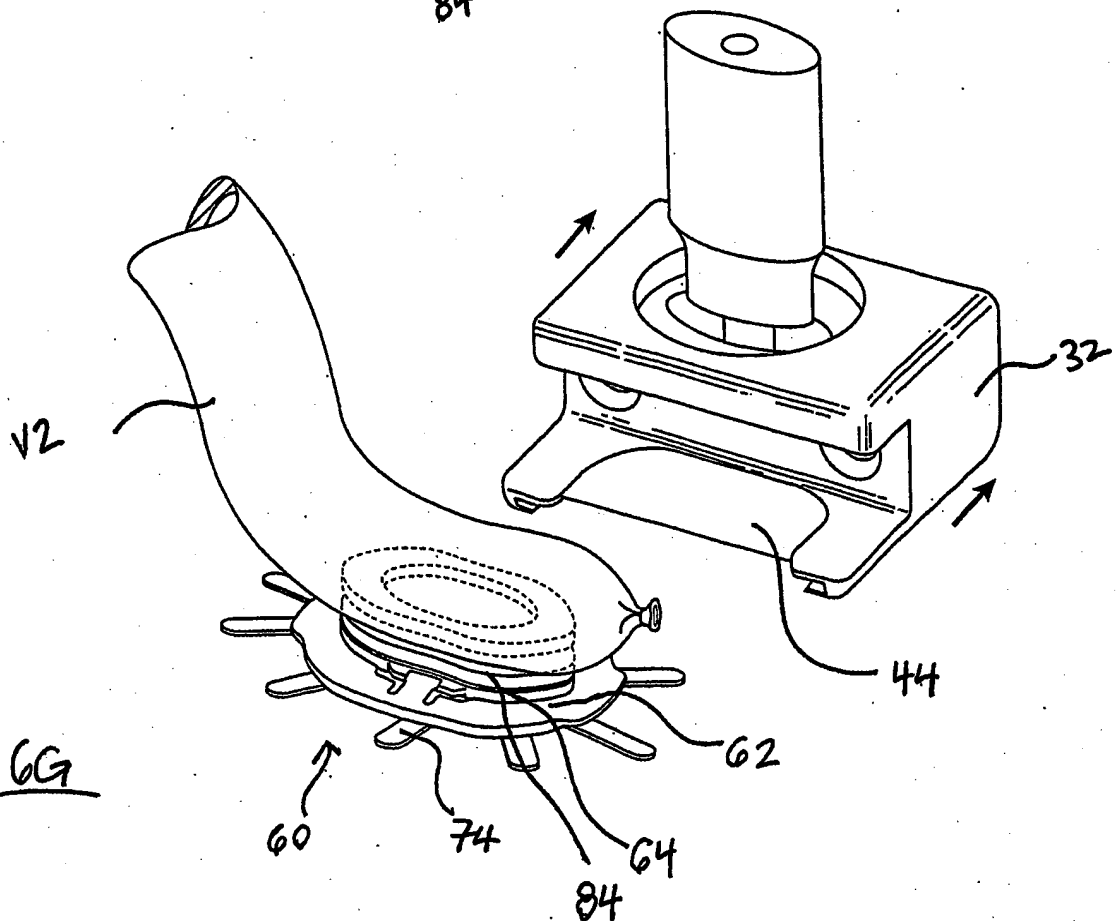


FIG. 7A

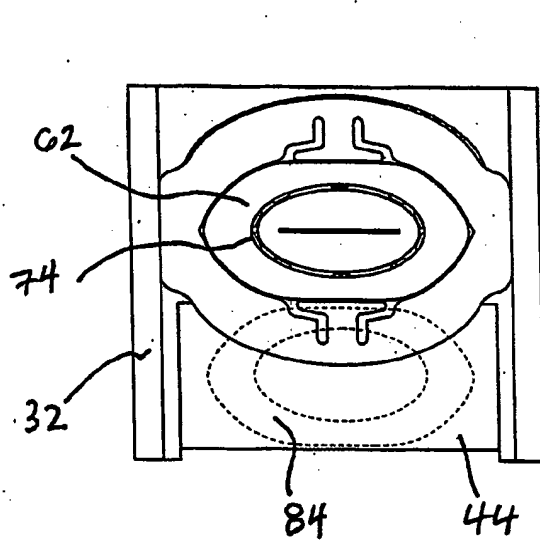


FIG. 7B

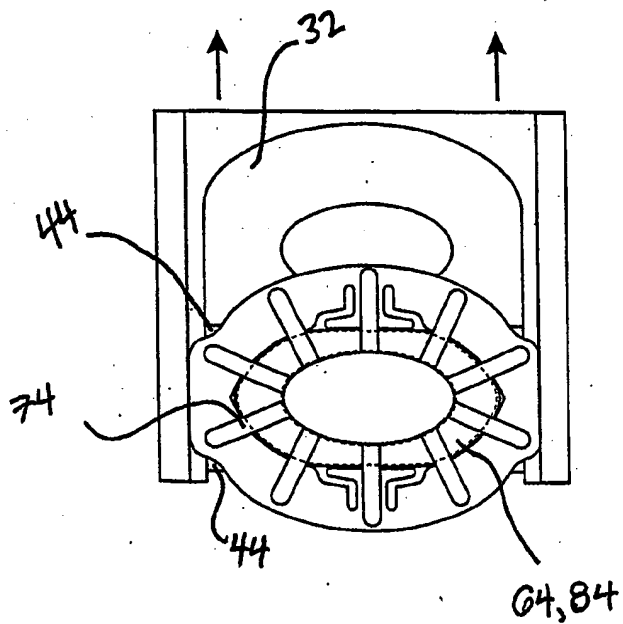
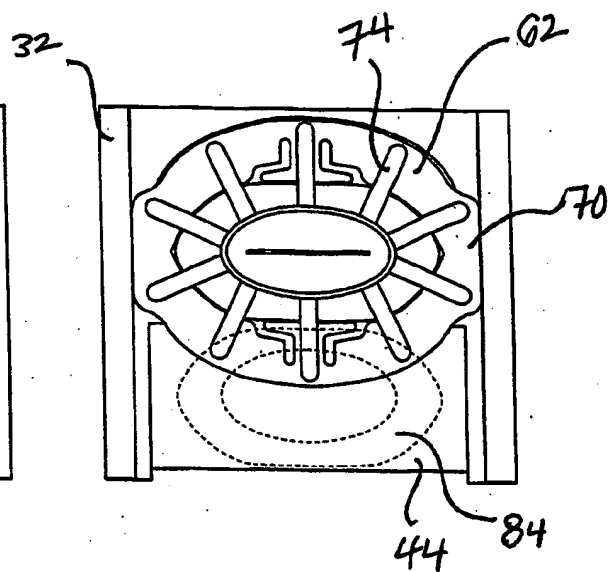


FIG. 7C

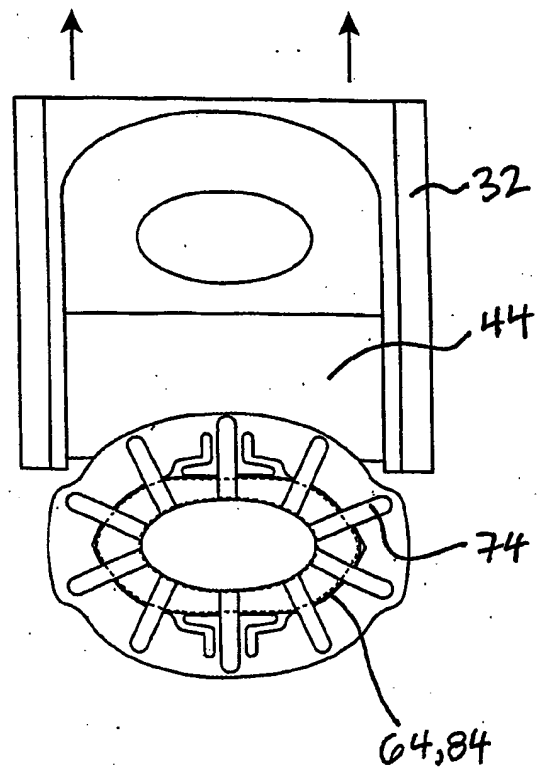


FIG. 7D

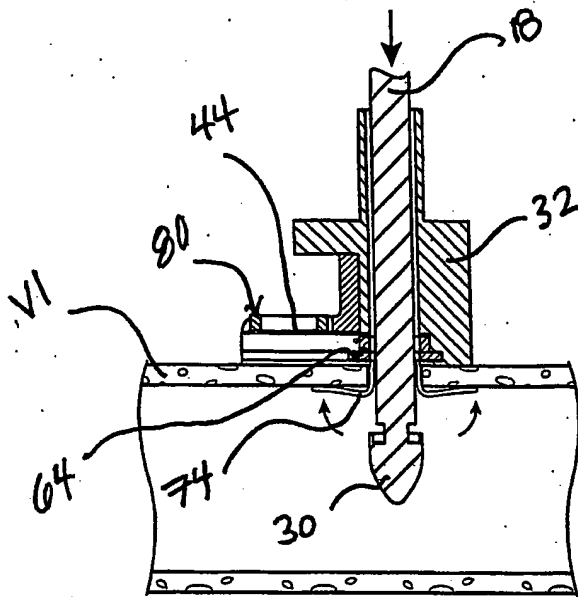


FIG. 8A

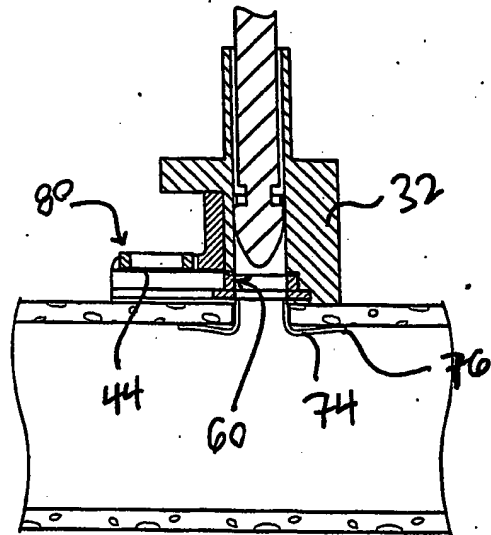


FIG. 8B

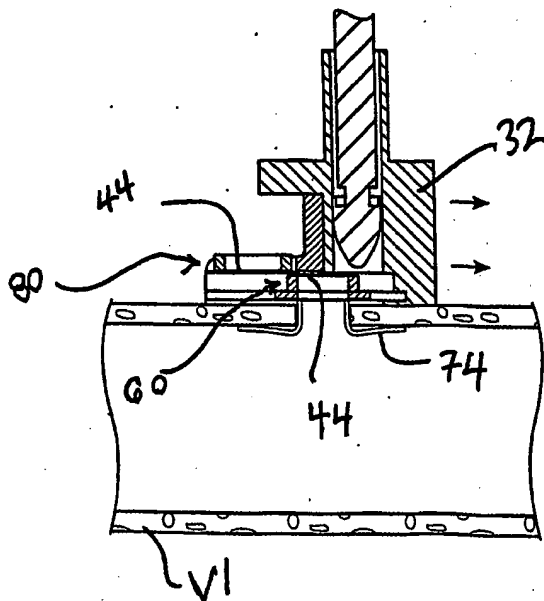


FIG. 8C

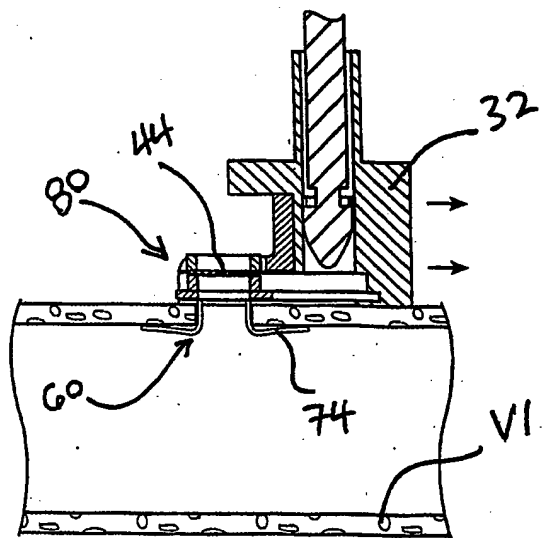


FIG. 8D

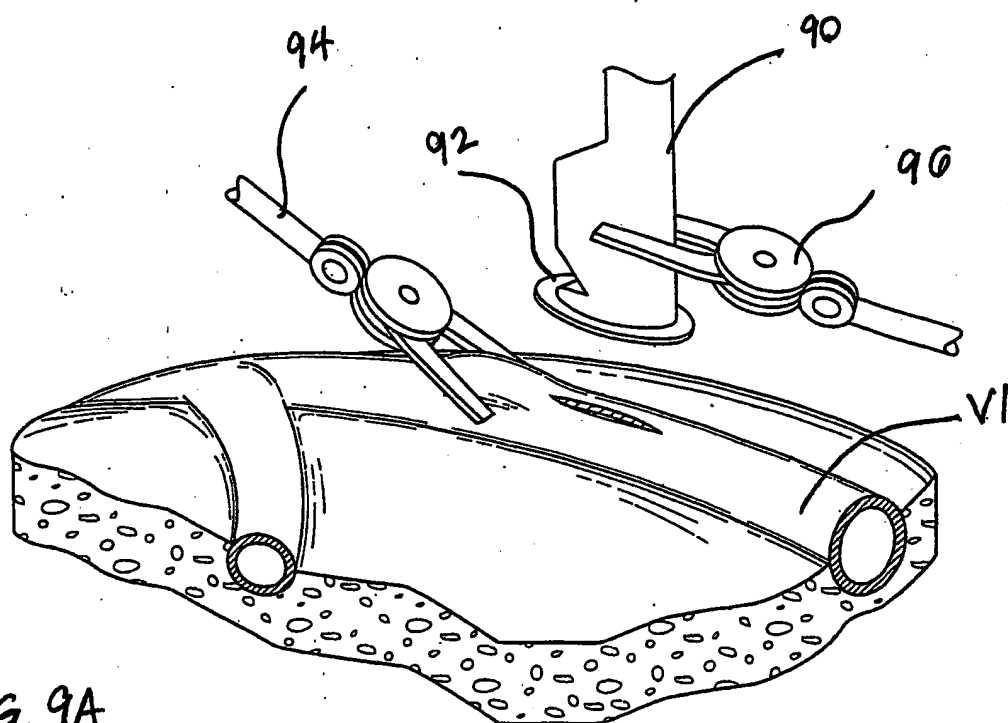


FIG. 9A

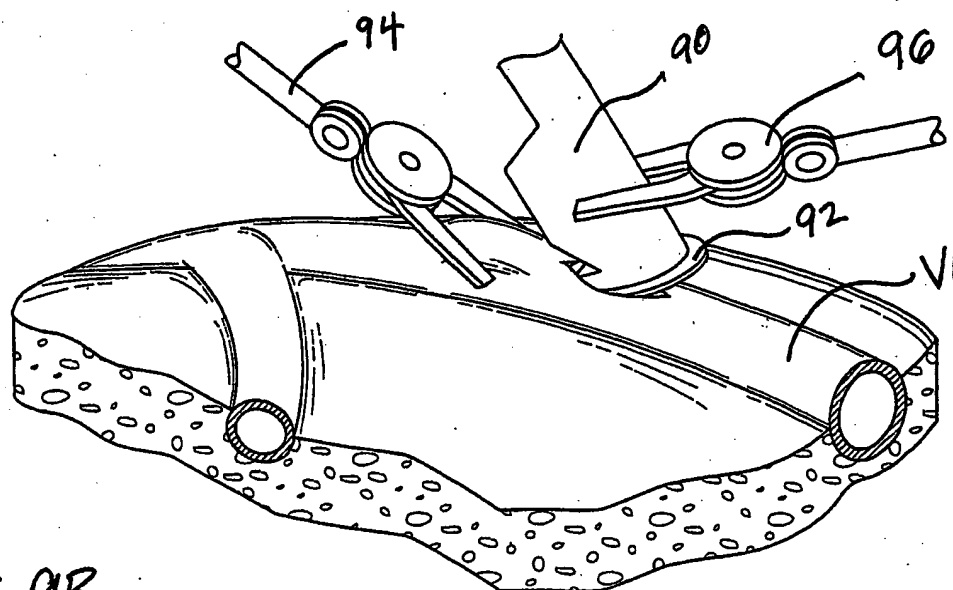
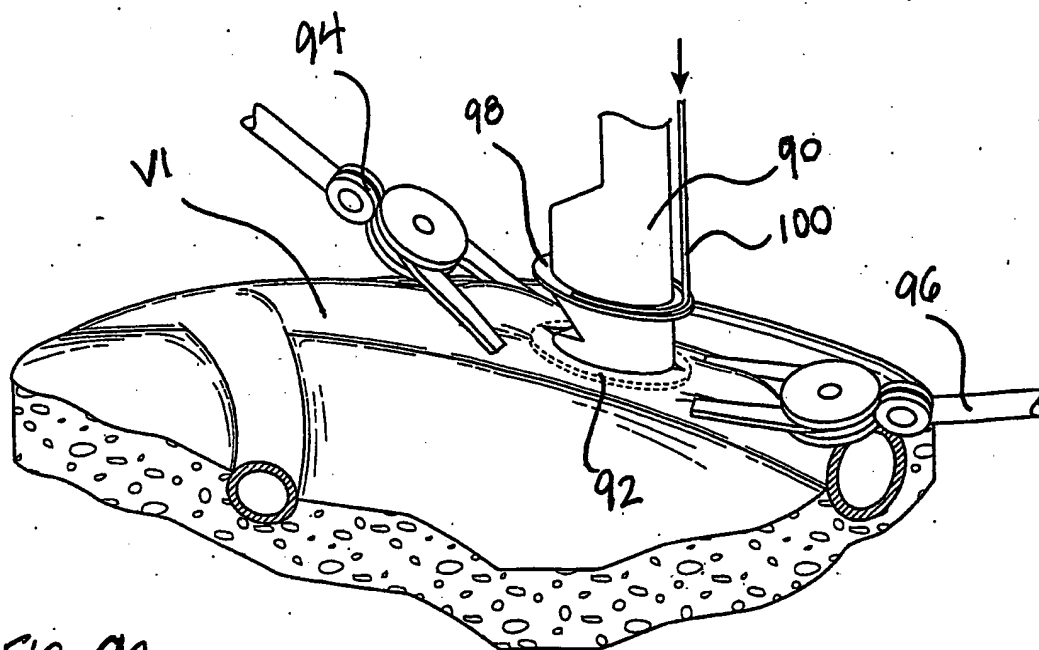
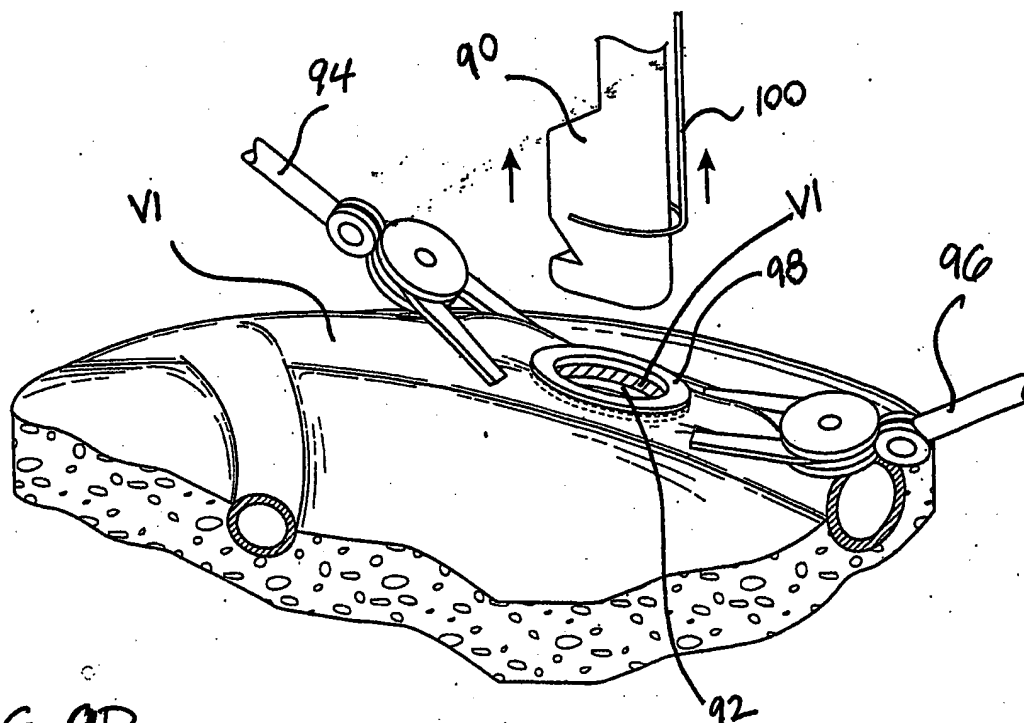


FIG. 9B

FIG. 9CFIG. 9D

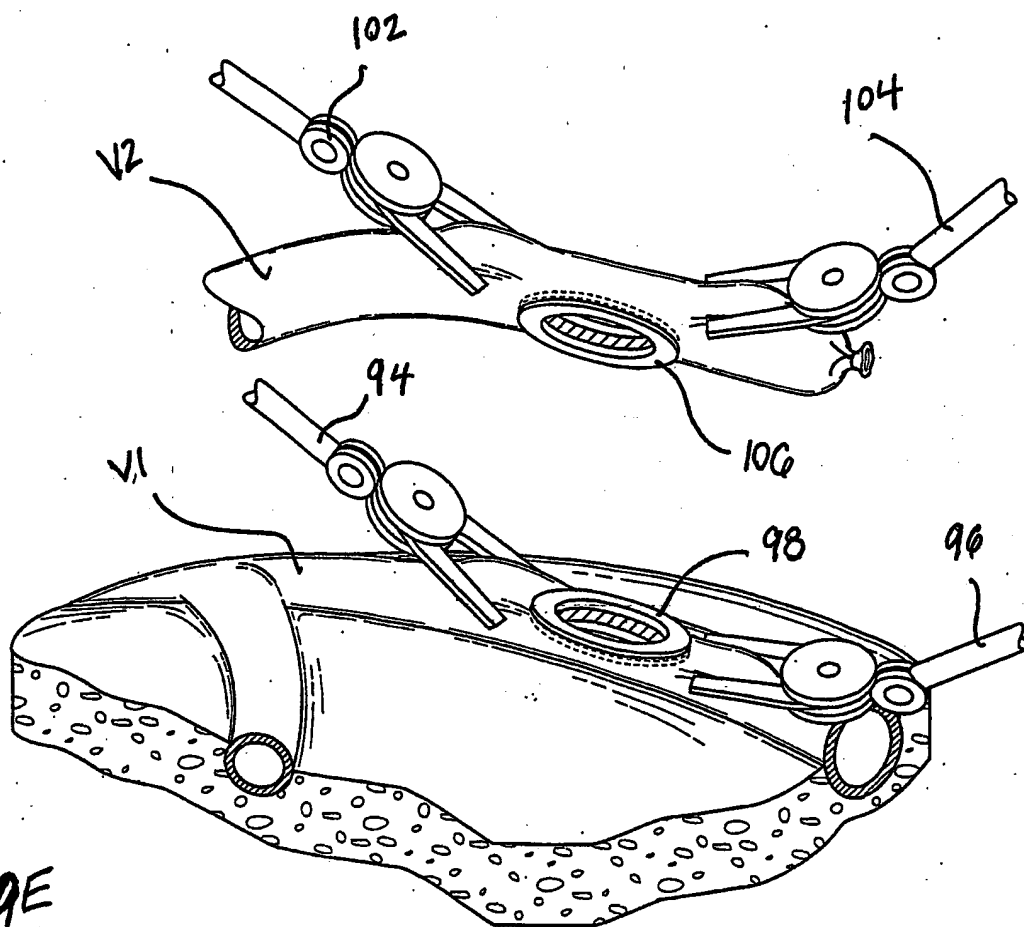


FIG. 9E

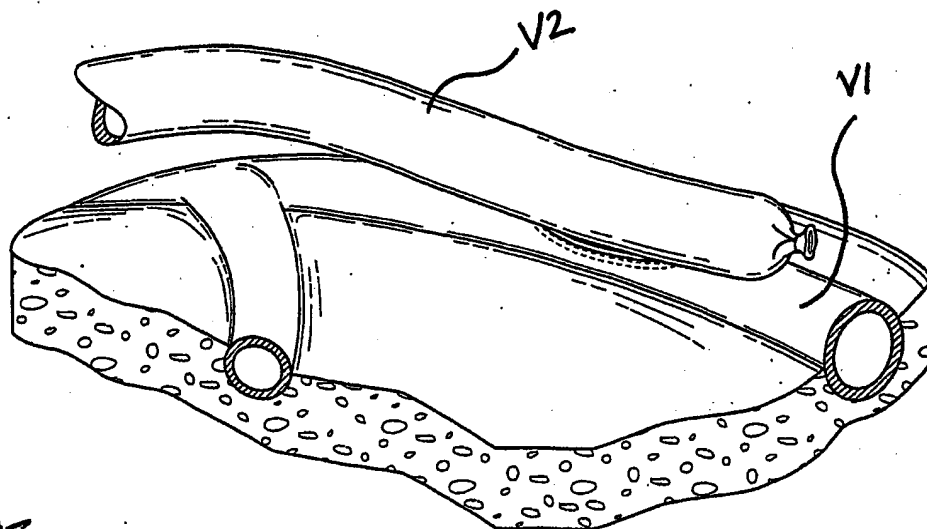


FIG. 9F

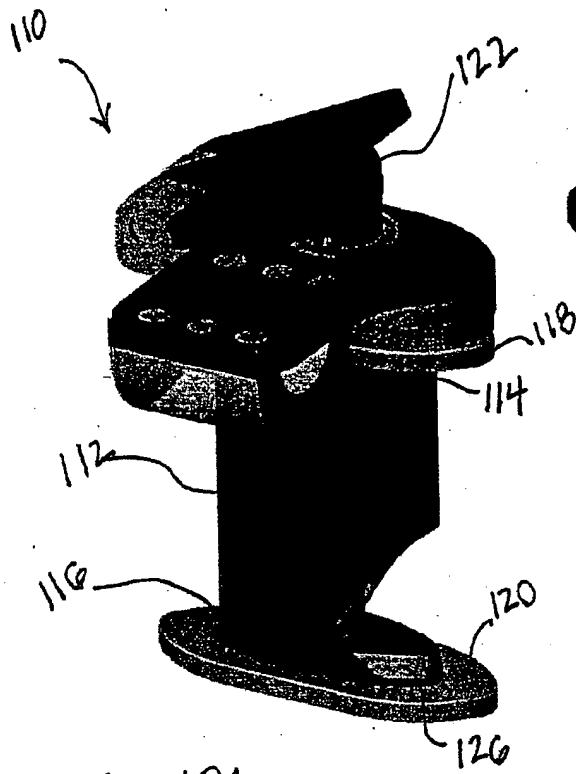


FIG. 10A

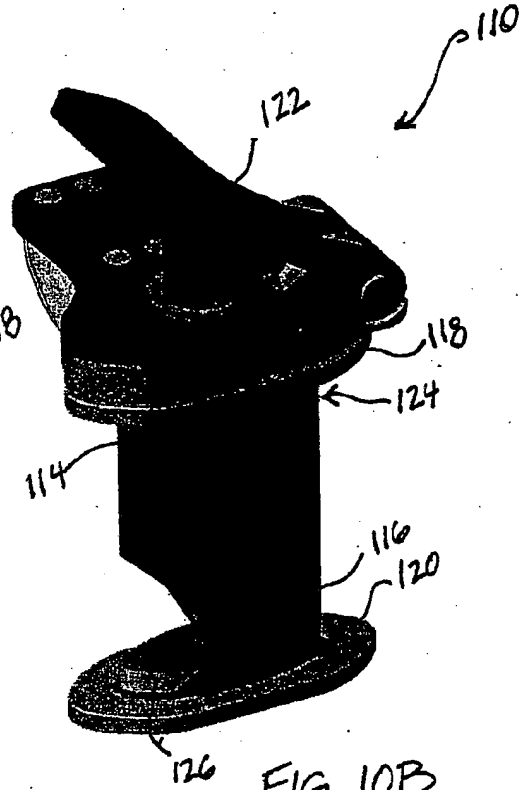


FIG. 10B

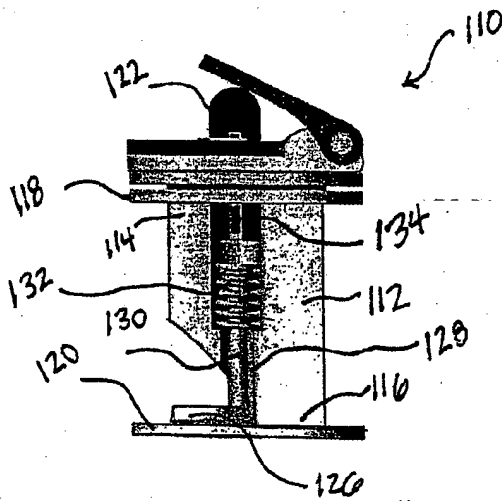


FIG. 11A

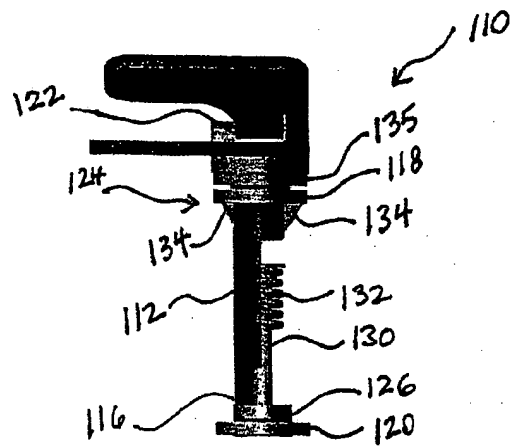


FIG. 11B

FIG. 12A

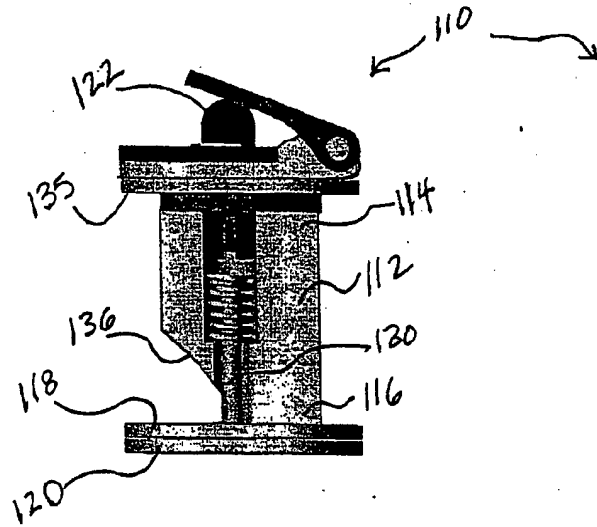


FIG. 12B

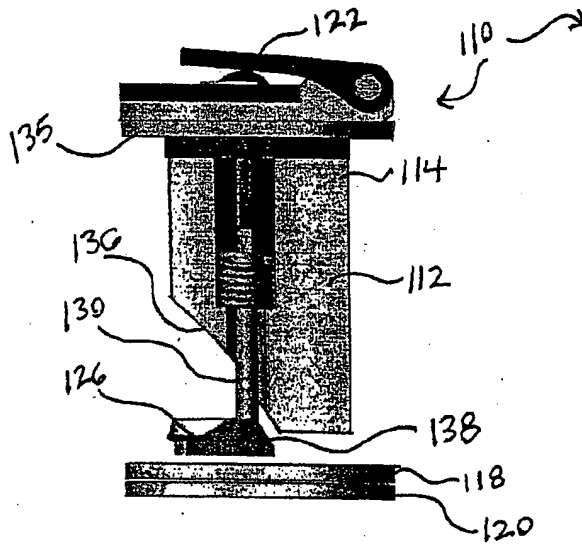
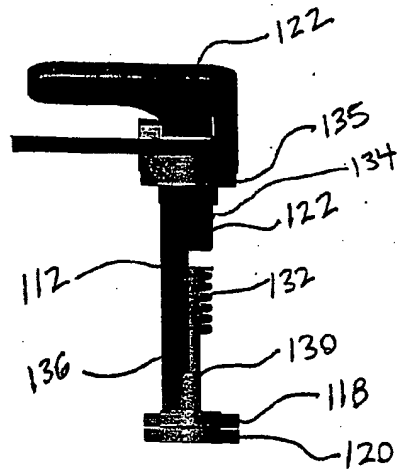


FIG. 13A

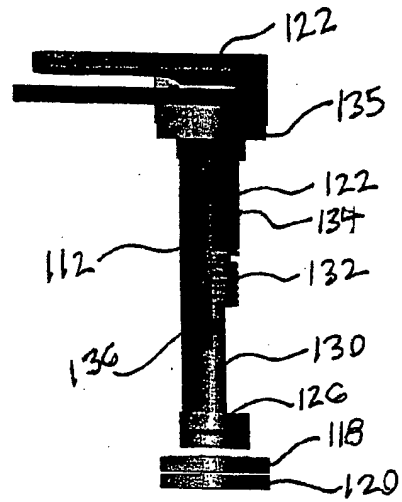


FIG. 13B

FIG. 14A

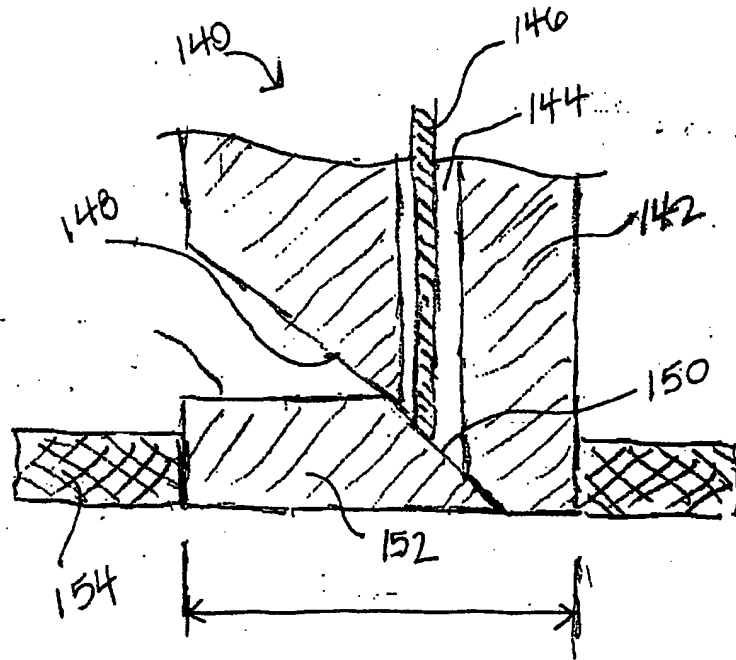
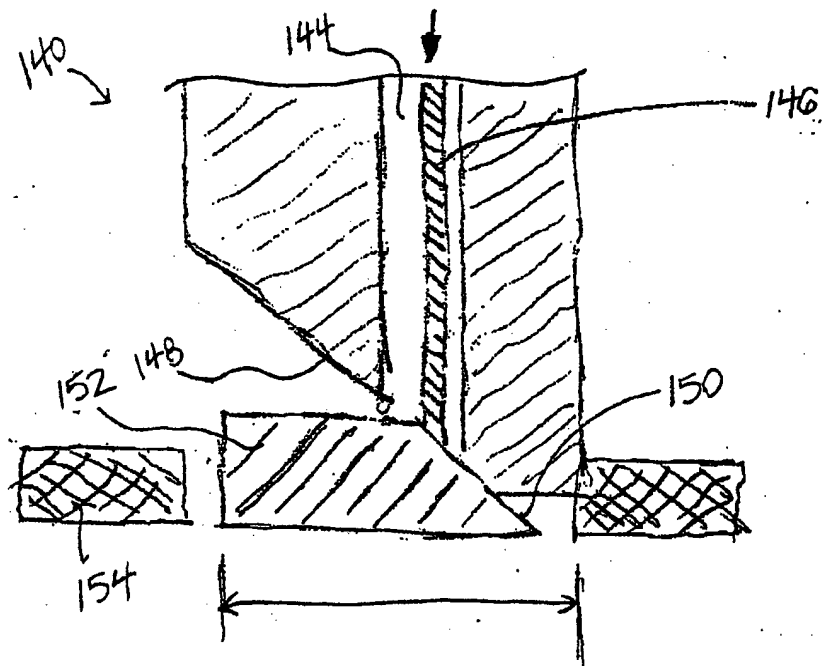


FIG. 14B



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(72) Inventors; and

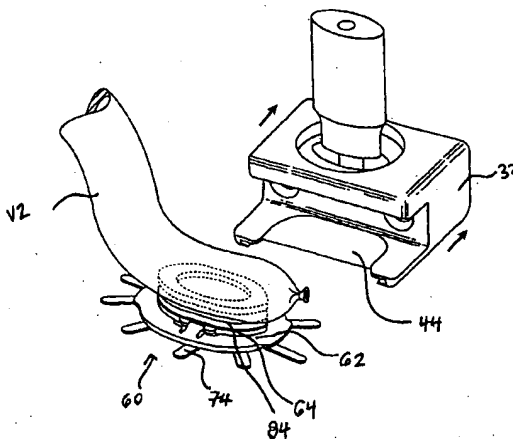
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[Continued on next page]

(54) Title: METHODS, DEVICES AND SYSTEMS FOR FORMING MAGNETIC ANASTOMOSES



(57) Abstract: Methods, devices and systems for forming magnetic anastomoses between two blood vessels. A first anastomotic component (60) is removably supported by the distal end of a delivery device (10) for attachment to a first vessel. The delivery device (10) also supports a second anastomotic component (80) that has been secured to a second blood vessel. The device (10) is operated to secure the first component to the first vessel, couple the second component (80) to the first component (60), and then release the components (60, 80) to complete the anastomosis. A robotic anastomosis system includes several robotic instruments (94, 96) that may be positioned through ports in a patient, used to secure an anastomotic component (60 or 80) to a vessel, and then used to magnetically couple the components (60, 80). Delivery devices (110) for deploying magnetic anastomotic components include an actuator (112) that uses magnetic repulsion to move the components (118, 120) into engagement with the inner and outer surfaces of the vessel wall. The anastomotic components (60, 80, 118, 120) are secured to the vessel wall by magnetic force and in addition may be secured by mechanical attachment.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/29485

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/08
US CL : 606/153

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 153-156, 167, 213, 216, 221; 128/898

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 6,352,543 A (COLE) 05 March 2002 (05.03.2002), see figures 22A-F.	1-50

<input type="checkbox"/> Further documents are listed in the continuation of Box C.		<input type="checkbox"/> See patent family annex.	
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>		<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>	
<p>Date of the actual completion of the international search</p> <p>30 November 2002 (30.11.2002)</p>		<p>Date of mailing of the international search report</p> <p>22 APR 2003</p>	
<p>Name and mailing address of the ISA/US</p> <p>Commissioner of Patents and Trademarks</p> <p>Box PCT</p> <p>Washington, D.C. 20231</p> <p>Facsimile No. (703)305-3230</p>		<p>Authorized officer</p> <p>Julian W. Woo</p> <p>Telephone No. 703-308-0421</p>	

INTERNATIONAL SEARCH REPORT

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Continuation of B. FIELDS SEARCHED Item 3:
EAST BRS
search terms: anastomosis, magnetic, robotic

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